Michigan Department of Agriculture

Training Program for the Professional Food Service Sanitarian

Module 7: Foodborne Illness Investigations

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A database of agents causing foddborne illnesses intended to assist regulators during investigations.

Introduction

We're going to be taking an in-depth look at the steps involved in an investigation from surveillance, to implementing prevention and systems control measures, right on through to the final report.

Reference points in a foodborne illness investigation from surveillance through the final report.

- Passive & Active Surveillance
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In the Food Microbiology module, we took a look at some of the bacteria, viruses, and parasites that can make us sick, as well as many of the controls for these pathogens. Now, in this Foodborne Illness Investigations course, we're going to draw on your previous knowledge and learn about investigative techniques that you'll use to help resolve foodborne illness outbreaks. We'll teach you how to track down pathogens and unsafe practices that may lead to widespread foodborne illness. You're going to learn to uncover underlying causes that will lead to practical solutions to foodborne illness outbreaks.

Food safety concerns have changed in the last several years. The global distribution of food has expanded our food choices. We hear about new pathogens like *Cyclospora* and new environments for existing pathogens such as *E. coli* O157:H7, *Cryptosporidium*, and *Salmonella* on fruits and vegetables. Food safety risks vary with the type of food and how the food was manufactured, distributed, stored, and prepared.

For example, until a few years ago, it was thought that you didn't have to worry about *Salmonella* in an acidic product like orange juice. We now know that *Salmonella* can survive in some acidic environments. The nature of foodborne illness has been changing in the last several years as well. In the past, outbreaks were typically local, on a relatively small scale, and focused in a certain area. There seemed to be some end-point contamination due to poor food-preparation practices. We still have these types of outbreaks, but in addition, today, we have foodborne-illness outbreaks that tend to be on a larger scale. They can be multistate or multinational, and sporadic and difficult to detect.

When a foodborne illness occurs, epidemiology is used to help us understand the who, what, where, when, how, and why the illness happened. **Epidemiology is defined as the study of the incidence, distribution, and control of health-related events in a specific population**. The primary objectives of a foodborne illness investigation are to stop the outbreak and prevent additional cases by implementing public health control measures. The epidemiological process can be applied in many different situations, but we are going to focus on foodborne illness investigations.

When an illness occurs, we want to find out the following:

- Etiologic/Causative agent
- Contributing factors

- Who is at risk
- Implicated food
- Mode of transmission
- When and where did the exposure occur

When an illness occurs, we want to find out what's the pathogen, agent, or toxin causing the illness; what factors contributed to the food contamination; and the survival or the growth of the causative agent; so illness can be prevented in the future. The Epi-process also helps us identify the exposure group or the population at risk; which food or foods are associated with the illness; the mode of transmission; the food or vehicle; and how the pathogen moves through the population. And finally, the process helps us identify the when and where, or the time and place of the outbreak. Using the Epi-process to answer these questions, food regulatory and health agencies are better positioned to control or prevent further exposure to the microorganisms and toxins (the etiologic agents) that cause foodborne illness. Lastly, information from epidemiological investigations is used to develop preventive control measures and to plan food safety programs.

Brief History of Epidemiology

Epidemiological thinking can be traced back as far as 400 BC to Hippocrates, the father of medicine. He was the first to approach disease in a logical rather than a supernatural manner, suggesting that environmental and behavioral patterns may influence the development of disease. In the 1600s, John Graunt, and later in the early 1800s William Farr, began to quantify information gathered on patterns of birth, death, and disease occurrence. In fact, William Farr is regarded as the father of modern vital statistics, with many of his basic practices still being used today. But it wasn't until around 1854 that the epidemiological investigative process was first noted. It centered on a cholera outbreak in London, England.

The title of "father of field epidemiology" was given to Dr. John Snow, an anesthesiologist who systematically investigated this outbreak in London. The area was called Golden Square, and Dr. Snow believed that water from one of the community wells was responsible for the cholera infection. That, in and of itself, is not notable, but the way he went about proving his theory is. Snow began by finding out where in the area the cholera victims lived and worked.

Using this information, he made a spot map showing the distribution of case households. Snow quickly found that more victims lived around the Broad Street pump than around the others, and he theorized that the Broad Street pump was the culprit. But again he had to prove it. So he went about questioning the residents who lived around the other pumps and discovered that they avoided pump B due to gross contamination, and pump C was too inconvenient. So from this, Snow conjectured that the Broad Street pump was the primary source of water for the Golden Square residents. But it still wasn't conclusive. He noted that there was a two-block area just down the street from pump A where no one got sick. How could this be, he asked? Probing some more, he found out that there was a brewery there with a deep well, and workers who lived in that block took their water from it. They also got a ration of malt liquor every day. That explained the one glitch in Snow's spot map. To confirm his theory, Dr. Snow questioned the cholera victims to find out where they got their water. He could now firmly state that water from the Broad Street pump was the one common factor among the victims. As the story goes, John Snow removed the pump handle and thus stopped the outbreak.[1]

Course Objectives and Goal

What we're going to do in this course is teach you how to "remove the pump handle" of a foodborne-illness outbreak. Just as Dr. Snow illustrated, we're going to step you through the sequence of an epidemiological process from descriptive

[1] Reference: Snow, J., *Snow on Cholera.* London: Humphrey; Milford: Oxford U. Press, 1936.

EPI to hypothesis generation to hypothesis testing to application of controls and preventive steps.

After completing this course, participants will be able to:

- Identify the rationale for developing and maintaining a surveillance system.
- Apply epidemiologic principles involved in a foodborne-illness investigation.
- Discuss the steps associated with investigating foodborne illness.
- Apply environmental investigation techniques for performing a food preparation review and identifying contributing factors.
- Identify and implement appropriate control measures to prevent additional illness.
- Discuss the role of the investigation team and the three main components: environmental, epidemiology, and laboratory.
- Discuss appropriate food and clinical samples to verify the agent.
- Be familiar with the terminology associated with foodborne illness investigations.
- Interpret descriptive and analytical data, measures of association and significance.
- Discuss the final report, ways to communicate findings, and implementation of preventive control measures.

The goal of the course is to improve foodborne-illness investigations to identify rapidly the implicated food and implement control measures to prevent additional illnesses; then utilize investigational findings for the present and future to prevent similar outbreaks.

Collecting Surveillance Data

Objectives

On completion of this module, participants will be able to:

- Describe a foodborne (and waterborne) surveillance system that includes the origins of surveillance data.
- Describe the reportable disease process in the United States.
- Compile and organize log data for a reporting period and observe deviations in frequency and distribution for specific illnesses.

Overview

In this module we're going to look at compiling data from several different surveillance methods; talk about the reportable disease process that we use in the United States; and discuss compiling and organizing a data log for a specific reporting period that will help you identify deviations in frequency and distribution of specific illnesses.

Surveillance Systems

- Ongoing collection, analysis and dissemination of information
- Monitor changes in disease frequency
- Establish background levels of specific diseases in a community
- Determine if changes in disease occurrence are related to time [seasonal]
- Linked to a place or host
- Analyze changes in endemic level of disease.

Surveillance systems help to answer questions like: How do you know when an outbreak of foodborne disease is occurring? Or how do you know whether a salmonella isolate is the first warning of an outbreak? Surveillance involves the ongoing collection, analysis, and dissemination of information. Using data collected from surveillance, you can monitor changes in disease frequency,

establish background levels of specific diseases in a community, or help determine whether changes in disease occurrence are related to time, such as the season of the year. Surveillance data can also be linked to a place (a specific geographic location) or even to a person or "host." Also, analyzing surveillance data over an extended period of time can help detect sudden changes in the usual background level of a disease, or "endemic" level of disease.

Various state and local departments and federal agencies are involved in disease surveillance to detect outbreaks. Surveillance attempts to link sporadic reports, such as a case of botulism, to a series of reports or a cluster of illness and outbreaks. Most of you should recall the "Schwann's ice cream" outbreak and the *E. coli* 0157:H7 case in the Pacific Northwest. Both are examples of outbreaks that began as little, sporadic reports and then rapidly expanded to multi-state investigations.

There are two kinds of surveillance methods: passive and active. First let's talk about passive surveillance. Most agencies use passive surveillance to find out about foodborne illness outbreaks. "Passive" is just like the name suggests: information comes to you; you don't seek it out. A department receives reports, alerts, or complaints of illness from a variety of sources, such as physicians, laboratories, other agencies, and, of course, the public. Many of these people complain of gastrointestinal (GI) distress or have flu-like symptoms and subsequently don't attribute their illness to food. It would not be unusual if they didn't go to their doctor. They may be simply saying, "Oh, it's just a bug that's going around." So only a small percentage of foodborne illnesses are ever reported to a physician. And we need to remember that physicians aren't required to report some foodborne diseases to the health department.

Even though requirements for reporting diseases are "mandated" by state laws, the list of reportable diseases varies from state to state. For example, prior to 1993, only a few states required the reporting of *E*. coli 0157:H7. Of course, today, most states require the reporting of this disease. (Editor's comment: Being reportable does not ensure that an illness will be reported to the health department, and being nonreportable does not preclude notification.) In 1997, 52 infectious diseases were designated as notifiable **at the national level,** and they're listed in this manual. The Centers for Disease Control (CDC) Web page address for the *Morbidity and Mortality Weekly Report* is:

http://www.cdc.gov/epo/mmwr/mmwr_snd.html

and the Web address for the list of infectious diseases designated as notifiable at the national level, United States, 1997, is:

http://www.cdc.gov/epo/dphsi/casedef/about97.htm.

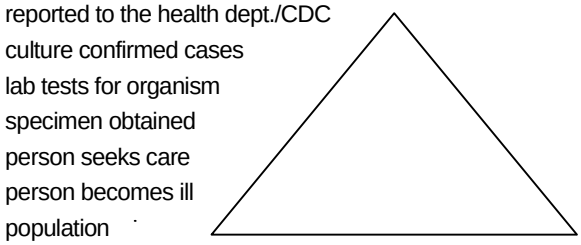
Infectious Diseases Designated as Notifiable

United States, 1997

Acquired immunodeficiency syndrome (AIDS)	Lyme Disease
Anthrax	Malaria
Botulism	Measles
Brucellosis	Meningococcal disease
Chancroid	Mumps
Chlamydia trachomatis	Pertussis
Genital infections	Plague
Cholera	Poliomyelitis, paralytic
Coccidioidomycosis	Psittacosis
Cryptosporidiosis	Rabies, animal
Diphtheria	Rabies, human
Encephalitis, California serogroup	Rocky Mountain Spotted fever
Encephalitis, eastern equine	Rubella, congenital syndrome
Encephalitis, St. Louise	Salmonellosis
Encephalitis, western equine	Shigellosis
Escherichia coli 0157:h7	Streptococcal disease, invasive, Group A
Gonorrhea	Streptococcus pneumoniae, drug resistant invasive disease
Haemophilus influenza, invasive disease	Streptococcal toxic shock syndrome
Hansen disease (leprosy)	Syphilis
Hantavirus pulmonary syndrome	Syphilis, congenital
Hemolytic uremic syndrome, post diarrheal	Tetanus
Hepatitis A	Toxic shock syndrome
Hepatitis B	Trichinosis
Hepatitis, C/non A, non B	Tuberculosis
HIV infection, pediatric	Typhoid fever
Legionellosis	Yellow fever

A physician will decide if a specimen is to be taken, and if necessary which lab tests to order. Obviously, if a specimen is not taken there is no lab test and nothing to report.

Burden of Illness Pyramid



To include foodborne illness in the passive surveillance system, the following steps have to occur: A person becomes ill, and the patient must go to a doctor.

The doctor must request specimens for analysis. The laboratory must analyze the specimen, the positive results must be reported to the health department, and the reports must be forwarded to the CDC. (Editor's comment: Some reporting systems do not require lab confirmation. Also, some states require that clinically diagnosed ailments be reported, even when laboratory confirmation is not available.) Some labs can test for a variety of microorganisms and use biomolecular typing to determine whether isolates are related to the same outbreak. Usually, tests for toxins, viruses, and parasites are run only if specifically ordered. Other labs have a more limited capacity and can run only routine tests.

Another example of passive surveillance is when someone becomes ill after eating at a restaurant and then complains to the health department. People who are concerned enough to take the time to file a report to a surveillance program want assurance that the appropriate person will be notified and that immediate action will be taken. Surveillance programs should be organized to receive and respond to complaints. The process for reporting should be quick and traceable to ensure that the appropriate person is informed regardless of the point of the first contact. The surveillance system should be "triage-oriented" (respond differently depending upon the circumstances) and should be able to proceed smoothly from one level of action to the next.

The surveillance system should have a referral process that ensures a timely and competent public health response. And finally, the system must be able to terminate effectively when resolution is reached and have a mechanism for feedback notification. If you try to analyze calls and complaints on an individual basis, it's difficult to determine the source of an exposure. That's where the surveillance log comes in. A surveillance log is simply a record of illness complaints.

Basic information in surveillance log:

- Date and time
- ID of affected person
- Event exposure info
- Geographic area

A log should include at least the date and time of the report, identification of the caller or the person affected, the event exposure information, and the geographic area. In the surveillance log example, the log shows a mix of reports including dog bites, measles, post-op *Staph* infections, and *Hepatitis-A*. On closer inspection, we see this log has three entries of *Hepatitis-A* within about two weeks of each other. All three are identified with the same day-care center. In general, the longer the incubation period, the further back the log must be reviewed for things like time, place, and person associations. If it is determined that follow-up contact is required, a note about the purpose and result of the

contact should be cross-referenced in the log so all personnel using the record will have access to the same information. We'll discuss the analysis and interpretation of the surveillance log in more detail later.

Example of a Surveillance Log, Week 2

Case #	Reported by	Time of report	Signs & symptoms, and lab results	Time of onset	Case's name, address, occupation & telephone #	Age	Sex	Possible sources of exposure, per reporting individual	Other similar cases
11	W. Hogan, MD 297-6834	1-17 3 p.m.	Hepatitis A Dark urine, clay colored stool, tired, jaundice	1-12	Billy Michaels 4211 Maple Drive	4	M	Unknown - attends Hillside Day Care Center	X
12	G.M. Miller, MD 458-2211	1-18 10:30 am	Meningacaccal Meningitis – headache, pain in legs, chills, fever, vomiting	1-14 5 p.m.	Anna Wilson Bay City	17	F	Unknown	
13	Anna Lewis 543-7918	1-18 10:45 am	Dog bite - puncture wound on left leg	1-18 am	Bobby Lewis 950 Rancho 543-7918	8	M	Dog's owner - Fred Allgood 695 E Rancho 543-8842	
14	W. Hogan, MD 297-6834	1-18 11:45 am	Hepatitis A Vomiting, fever, dark urine, jaundice	12-31 7 p.m.	Idda May Jones 127 Hill Circle Cook at Hillside Day Care Center	42	F	Unknown - visited relative early in December	X
15	F. Diaz, MD 223-8846	1-18 2 p.m.	Measles, fever, rash	1-14 8 am	Joey Hernandez 72 Rancho Road 224-7713	3	M	Unknown - attends Hillside Day Care Center	
16	S. Menousek, MD 764-0241	1-18 2:45 p.m.	Hepatitis A	1-13	Susie Smith 238 Taft Street 448-7283	4	F	Unknown - attends Hillside Day Care Center	X
17	James, Mitchell, MD Brassfield Hospital 247-8900	1-18 3 p.m.	Post op., staphylococcal infection	5 cases since 1-1	5 cases - hospital has records		F	All are post op in general surgery wing	

Passive surveillance

Passive surveillance has its advantages…

- Inexpensive
- Can detect rare events
- Can suggest hypotheses about causative factors
- Likely to represent illnesses with a short latency/incubation

…and disadvantages…

- Bias due to self-selection
- Don't know total exposed and lack comparison groups
- Others have incomplete reporting of events

A big advantage of passive surveillance is the relatively low cost. Passive surveillance can detect rare events, and it's a good resource for suggesting causative factors, especially for illnesses that have a short incubation or "latency" period. There are also a few limitations. For instance, the data is biased due to self-reporting: here tends to be incomplete reporting, and you will not know the total number of people exposed.

Active Surveillance

With active surveillance you seek out illness information. You actively examine such things as hospital discharge records, laboratory records, and medical examiner reports. (Editor's comment: You can also contact pharmacists to learn about increased sales of over-the-counter medications for specific illnesses such as diarrhea.) Sometimes you may even establish sentinel sites. **A sentinel site is a type surveillance system used to track diseases caused by specific pathogens, and to determine the rates of illness in a clearly defined geographic area.**

Active surveillance also has advantages…

- More accurate
- Measures exposure and illness estimated time relationships
- Determine circumstances

…and disadvantages…

- Additional resources needed
- Expensive

The data in an active surveillance system is more accurate compared to a passive system. It allows you to measure illness. You can also estimate time or temporal relationships. And you can determine circumstances associated with illness. The downside of actively searching for information is the additional resources required. Active surveillance is expensive. Another important aspect of maintaining surveillance is that someone must be responsible for the continuous operation of the surveillance system.

Operating a Surveillance System

- Responsibility for monitoring surveillance system
- Organize and interpret data
- Communicate to public health personnel
- Trained in EPI methods
- Monitor and evaluate data
- Establish base-lines
- Identify coordinating agencies and individuals
- Cross train back-up staff

Data must be organized, interpreted, and communicated to public health personnel on a regular basis. The person assigned to surveillance should be trained in EPI methods. They should monitor and evaluate data, establish baselines for communicable diseases, identify agencies and individuals to coordinate with, and cross-train backup staff to operate the surveillance system. Here are some things you need to do to develop sources of information.

Network with medical care facilities such as hospitals, emergency rooms, clinics, health maintenance organizations (HMOs), managed health care organizations, laboratories, poison control, and urgent-care centers. An effective and active way to foster interaction is to provide sampling kits to facilities such as emergency rooms (ERs). The facilities will use the kits to collect samples from food brought in by patients or for collecting any clinical specimens. Remember: No samples – No lab tests – No information.

You also need to develop a list of people, addresses, and telephone and fax numbers, and if possible, e-mail addresses for notifying appropriate personnel during emergencies. It's extremely important to encourage others to notify your department when they encounter or suspect foodborne illness. Another way to improve surveillance is to have a prominent telephone listing for reporting foodborne illness, like a 24-hour hot line, an answering service, or some other innovative means of receiving and answering after-hour calls.

FoodNet

Working together, the CDC, U.S. Department of Agriculture (USDA), and Food and Drug Administration (FDA) have implemented an active foodborne disease sentinel site surveillance program called FoodNet**.** FoodNet is the name given to the laboratory-based active surveillance system for tracking sporadic cases of foodborne disease. The CDC, FDA, and the USDA established FoodNet in 1995,

and the system operates in portions of California, New York, and Maryland and is statewide in Oregon, Minnesota, Connecticut, and Georgia.

The pathogens tracked by FoodNet include *Salmonella*, *Shigella*, and *Campylobacter*, *E. coli* O157:H7, *Yersinia*, *Vibrios*, *Listeria* monocytogenes, *Cyclospora* and *Cryptosporidium*. FoodNet has several components including a survey of clinical laboratories that receive specimens from persons who reside in the geographic catchment areas to determine what organisms the labs are testing for.

Components of FoodNet include the following:

- Survey of clinical
- Routine contacting of labs
- Survey of physicians who see patients with diarrheal disease
- Population survey of persons in catchment area
- Case-control studies

FoodNet provides a survey of physicians who see patients with diarrheal disease to determine their criteria for requesting stool testing. FoodNet also gives you a population survey of persons who reside in the catchment area to determine the frequency of diarrheal disease and risk behaviors, and finally it provides case-control studies on the patients to identify risk factors and other epidemiologic features for the various organisms of concern.

When we put all these components together, we get a kind of insight that we could never get before. We're now able to estimate actual levels of illness in the general population by calculating backward from the clinical laboratory findings. By spreading our coverage over several states, we can detect some of the very widespread sources of illness, and we can also tell whether anyone of our sites is experiencing an unusual upturn or downturn in a particular disease.

PulseNet

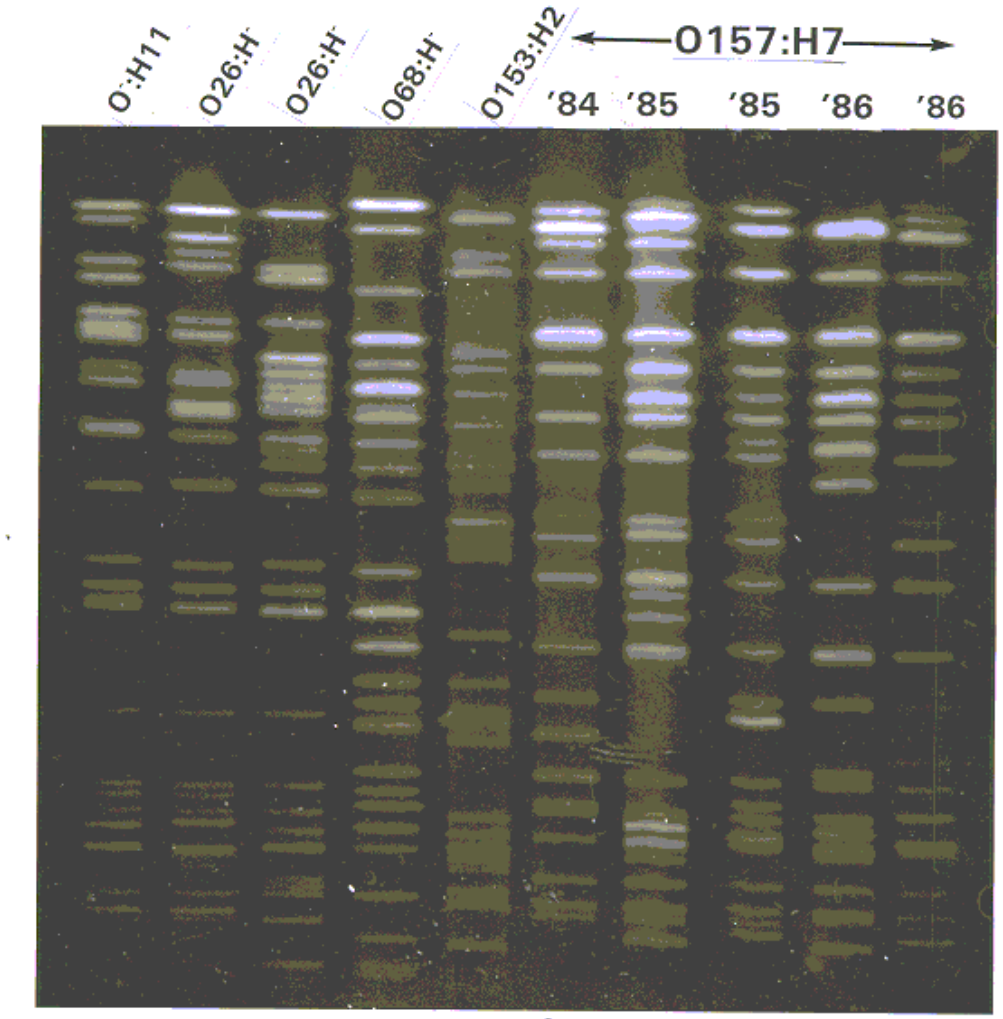
In addition to FoodNet, an electronic bacterial subtyping and communication system called PulseNet has been set up between the State health departments, FDA, USDA, and CDC. PulseNet is a multiagency effort that was officially launched in May 1998. This partnership is designed to assist in epidemiological analyses such as tracebacks and cluster identification. This network was made possible by the conjunction of three powerful tools: the highly discriminating DNA fingerprinting method of Pulsed-Field Gel Electrophoresis (PFGE); the use of a customized software that allows computerized analysis and databasing of the PFGE patterns; and the Internet, which allows us to transfer large image files and data between participants. These tools, harnessed using standard protocols, now allow for the rapid comparison of foodborne bacteria isolated from different parts of the country. Currently, the system includes the CDC, USDA, FDA, two

counties, and more than 25 State health departments. It will expand to cover most of the United States by the year 2000. At present, the system is monitoring all *E.coli* O157:H7 isolates, while other species are analyzed on a case-by-case basis. The system tracks clinical, food, and environmental isolates from food production facilities that are implicated in outbreaks. Eventually, the system will cover most of the key foodborne bacterial pathogens and will be linked to similar networks overseas.

DNA fingerprinting (Pulsed-Field Gel Electrophoresis; PFGE)

The PFGE method, developed in the 80's and recently condensed to a one-day procedure, uses a special electrophoresis technique to separate mixtures of very large DNA molecules into a barcode-like pattern called a DNA fingerprint.

Bacterial cells are imbedded in a gel matrix. Then a series of enzymes and chemicals are used to remove all the cellular components except the DNA, which is obtained in an intact and pure form. This DNA is digested with a restriction enzyme that cuts it into a specific set of fragments. These fragments are separated by PFGE, and the resulting pattern is digitally imaged after staining. By comparing the PFGE patterns of two or more isolates, we can determine how closely related they are; this relationship analysis is key in cluster analysis as most point-source clusters are caused by clones of a single PFGE pattern type.



In the Pulsed-field Gel Electrophoretic analysis of enterohaemorragic E. coli (EHEC) isolates, significant differences were visible among the genomic patterns of strains representing serogroups O:H11, 026:H, 068:H and 0157:H7. Marked differences were also noted between the two 026:H isolates (lanes 2 & 3) as well as amongst 0157:H7 strains isolated between 1984-86 in the USA (lanes 6-10). This reveals that genomic restriction pattern heterogeneity exists not only among different serogroups of EHEC but also within serogroups. This diversity adds to the value of PFGE in subtyping EHEC isolates. Further, illnesses in the United States attributed to EHEC are not caused by a single strain.

Roles of Computerized Pattern Recognition and the Internet in the PulseNet Project

The DNA fingerprints generated by a participating site are relayed to a central computer at CDC in Atlanta. Here, after a quick QA/QC check, they are stored and then compared, using software specifically designed for PFGE pattern analysis, against all the fingerprints of that species submitted by the other sites. If a close match is found between fingerprints submitted within 30 days of each other, an automated e-mail is sent to all the sites, alerting them and providing the

basic epidemiological data associated with those isolates, such as the food implicated. This allows outbreak investigators to better focus efforts and resources in their quest to identify and control the sources involved.

PulseNet and Public Health Microbiology

PulseNet speeds up the comparison of isolates that are suspected of being linked. Previous to PulseNet, the only way two isolates could be compared was if they were analyzed at the same location; this required the mailing of isolates from one site to another, with an additional delay while DNA was repurified at the new location. Also, while the epidemiological analysis of large outbreaks that occur in a short period of time is relatively easy, small clusters of cases that share a common cause were often misidentified as sporadic. The steady flow of data from what appears to be sporadic cases allows us now, using PulseNet, to spot diffuse clusters and take remedial action in a timely manner. Such genetic monitoring of apparently sporadic cases also serves as an early warning system for emerging pathogens, such as multidrug-resistant strains, that are of elevated public health importance.

Example of PulseNet Success

Even though PulseNet is still in its infancy, it has already proven its value in a number of cases. A good example is where an unambiguous match was found between the DNA fingerprints of *Shigella sonnei* isolated and analyzed by a number of PulseNet participants in the US. In some of these cases, imported parsley was implicated, while in others the responsible food was not clear. After PulseNet linked the various cases together, detailed traceback analysis showed that either parsley or cilantro from the same operation in a foreign country was involved; the PFGE provided the definite evidence needed for a regulatory response to the situation, thus preventing further cases of illness from this source. Similarly, PulseNet has been invaluable in tying together multistate outbreaks caused by *E*. *coli*, *Listeria* monocytogenes and *Salmonella* agona.

Planning for the Investigation

Objectives

On completion of this module, participants will be able to:

- Identify the equipment necessary to investigate foodborne illness.
- Understand the need for a multi-disciplinary outbreak investigation team.
- Understand the need for coordinated efforts between agencies during outbreak investigations.

Equipment

Part of surveillance is being prepared for emergencies because we all know, sooner or later, you'll have an outbreak. Being prepared for an outbreak includes having your equipment and team ready to go. The investigation will go a lot smoother if you have the necessary equipment, documentation forms, and sampling kits ready for use when you need them. In this module we're going to talk about developing an equipment checklist and collecting the necessary supplies so you can be ready to go at a moment's notice.

Make sure that you have your aseptic sampling equipment all set to go. An important point to remember is some sterile equipment and supplies have a limited shelf life, so pay attention to expiration dates. Talk with the laboratory and develop replacement schedules for supplies. Restock supplies as they are used up or exceed the expiration date. Sample integrity can be questioned if improper equipment or out-of-date supplies are used to collect the sample.

By following proper sample collection procedures, you will ensure that any microbial contamination found during analysis did not come from the sampling equipment. After all, it's better to be part of the solution than part of the problem! Sampling guidelines will identify the equipment used for collecting various samples. You can use the guidelines for organizing the outbreak equipment.

Food and environmental samples are collected primarily to identify or verify the agent. In other words, if your suspect pathogens are, let's say, *Campy* or *Salmonella* or *Shigella*, your environmental samples are taken to prove your suspicions. There is an extensive list of forms and equipment in the course manual.

Having the necessary equipment to perform the inspection and aseptically collect samples is important. If improper equipment is used to collect samples, then sample integrity will be questioned and samples will be meaningless. The following is a suggested equipment checklist. The list should be modified depending on product and inspection requirements.

- affidavits
- alcohol wipes
- batteries
- Betadine solution
- boots
- camera
- check strips for checking sanitizing solutions: Chlorine, Iodine, Quaternary, Ammonia
- Cups
- dippers
- drill and drill bits for taking core samples
- embargo and detention tags
- enteric stool kits (sterile)
- film
- flash (for camera)
- flashlight, with extra bulbs
- forceps
- garbage bags
- gloves
- hair net

- hammer
- hat
- inspection and observation forms
- jars (plastic, wide-mouth with screw lids)
- knife
- lab coat
- labels (stick-on type)
- FDA-482 - Notice of Inspection
- FDA-483 - List of Observations
- FDA-484 - Receipt for Samples
- laboratory submission forms
- masking tape
- money
- notices (voluntary condemnation, correction and closure)
- packing tape
- paint cans, gallon size (sterile)
- paper clips
- paper bags
- parasitic stool kits
- plastic bags (sterile)
- rubber bands
- scoops (sterile)
- small propane torch (for on-site sterilization or disinfection)
- spark igniter
- spoons (sterile)

- stop Watch
- swabs (sterile)
- tape (stretch type)
- temperature measuring devices; a bayonet thermometer, a thermocouple, a thermistor, a temperature data-logger, and maximum registering thermometers
- tongs (sterile)
- tongue depressors (sterile)
- waterproof markers
- Collect Report
- FDA-525
- Sample Seals
- Government shipping stickers/bus bills
- Copies of information from files

Outbreak Investigation Teams

Let's not forget the people when preparing for an outbreak. Conducting a foodborne illness investigation can be a huge, time-consuming task; don't go it alone. Your team should be composed of professionals from multiple disciplines such as epidemiologists, sanitarians, inspectors, investigators, environmental health specialists, public health nurses, microbiologists and other laboratory scientists, public information specialists, and office support personnel. As with assembling the investigational equipment prior to an outbreak, assemble your team. Once an outbreak occurs, it's more difficult to get organized.

Teams work best when there is a common understanding, respect, and trust among the team members with all parties focusing on the goals of resolving the outbreak. This means working together and focusing on the outbreak. The goal is to stop the outbreak and learn from the experience. Work cooperatively, focus on the task, and respect differences of opinion. It's a matter of being attentive and maintaining constructive relationships. Take the initiative to make things better: lead by example.

With the different disciplines involved, who does what on the team will vary. The important thing is that the various tasks and responsibilities involved with the investigation are assigned to individual team members before the next outbreak. Each member should be accountable to the team to follow through with assignments and participate in the group process. Roles and responsibilities

should be established ahead of time. Questions like: Who is team leader? Who are the backups? Who is point person for the media? How do we coordinate these activities and notify each other? …should be considered before you're in an emergency situation.

Outbreak Team Leader

How your team is formed with the breakdown of roles and responsibilities will depend upon how it works best for you. For example, not every jurisdiction has an epidemiologist, but every state has one. Many teams will have to establish protocols in consultation with their state epidemiologist, lab, and nurses and others. Someone has to be the leader and central hub for the flow of information and open the lines of communication. The position of team leader is not necessarily a supervisory role. Typically the team leader may not have direct authority over the individuals comprising the team. The members should view the arrangement as a temporary job matrix during the outbreak where team members provide input, perform specialty functions, and report findings to the team leader. At the conclusion of the investigation, individuals return to their routine assignments.

The team atmosphere should be open for consensus building. Encourage constructive input and brainstorming to generate all those wild and sometimes crazy ideas and potential "could be's" or "what if" scenarios in trying to figure out what happened. Also with this process, the pros and cons of a decision can be weighed by the group before its implementation: a kind of check-and-balance process to reduce the chance of error or overlook possibilities that should be considered.

Between outbreaks, team meetings can be regularly scheduled to build rapport within the team and fine-tune procedures. After your next outbreak, evaluate the investigation as a team, keep what worked well, refine what didn't work, and conduct in-house training to enhance skills. Attending seminars keeps staff current and provides opportunities for networking with other agency personnel. It's also a good idea to start a library with information on foodborne illness and keep it current as new and emerging pathogens are reported. Once an outbreak occurs, the team should be prepared to go. Holding daily meetings to review findings and keep everyone up to date is important.

The foodborne illness investigation can be visualized as a three-legged stool. The investigation process has three components: EPI, laboratory, and environmental.

Without all three legs secure, the stool will fall over, toppling the team. Sometimes an outbreak will cross jurisdictional lines and require cooperation between investigation teams on the local, state, and federal levels. For example, in 1997, a *Hepatitis-A* outbreak in the Midwest involved strawberries served with the school lunch program. What started out as a local outbreak went multistate, and the investigation ended up including many state and federal agencies. When multiple agencies are working on the same outbreak, interagency communication becomes extremely important. Before the next outbreak, identify cooperating

agencies, establish two-way communication and coordination procedures with these agencies, and include a contact person, emergency phone and fax numbers, and e-mail addresses.

The success of an investigation comes down to thorough work, notification protocols, and networking. Leaving a department out of the loop can hinder an investigation; besides, it's an exercise in courtesy and diplomacy. Would you rather be questioned on a pending outbreak by the press or informed by a counterpart? Everyone knows the answer to that question. Typically, large outbreaks initiated at the local level progress to the state level.

Depending on the circumstances such as interstate commerce, the size of the outbreak, and the agent involved, federal notification by the state may take place.

USDA/FSIS/Meatborne Hazard Control Center; 1-800-535-4555

If the implicated or suspected food item is meat, poultry, or some egg products from a USDA-regulated plant, then the USDA would be notified through compliance officers in the field or directly into USDA's Consumer Surveillance Information System. Consumer complaints are also received on USDA's Meat and Poultry Hotline. So there are several channels through which information can flow.

Generally speaking, all other food products except domestic meat, poultry, and some egg products in interstate commerce fall under the FDA's jurisdiction. Typically, the state would contact its FDA District Office, and the district office would then notify the Division of Emergency and Investigational Operations in the FDA's headquarters. The district offices and DEIO also receive complaints from the public. If a complaint goes to the wrong agency, both FDA and USDA forward appropriate complaints back and forth and work together in investigations as necessary. Another example of teamwork!

EPA

In waterborne and environmental related outbreaks, the state may notify the Environmental Protection Agency (EPA). If there is a potential of contaminated drinking water coming into contact with foods in a processing plant or slaughterhouse, then both FDA and USDA would become involved. An example of interagency cooperation was the *Cryptosporidium* waterborne outbreak in Milwaukee, Wisconsin.

FORC-G

Depending on the size and nature of the outbreak, the pathogen involved or the need for certain lab tests, CDC can provide expert advice and assistance when requested. All federal agencies network and assist each other and the states, as appropriate, for foodborne illness investigations. The federal, state, and local agencies have developed a network called FORC-G, (pronounced "force-gee") "Foodborne Outbreak Response Coordination - Group." This outbreak evaluation

group consists of the heads of various federal, state and local agencies to improve and coordinate the approach to multistate outbreaks. The FORC-G group reviews operations and networking after interstate outbreak investigations to see what worked well and what procedures could be improved or refined to develop standard operating procedures.

Good teamwork and strong communication are vital for resolving foodborne outbreaks. If your department does not already have a foodborne illness investigation team, then develop a plan. If you already have a team, then reevaluate procedures to make sure everything is the way it's supposed to be. Now that we've discussed planning for the investigation, let's move on to beginning the investigation.

Beginning the Investigation

Objectives

On completion of this module, participants will be able to:

- Gather useful information on complaints.
- Understand the significance of time of onset of symptoms, as well as, associations by time, place, and person.
- Be able to develop a hypothesis and case definition.
- Be able to outline an appropriate follow-up strategy to a potential foodborne illness outbreak.

Gathering Complaint Information

Reports of illness can come into the health department piecemeal. When a complaint is received, try to get as much information as possible up front. Trying to establish the relevant facts is difficult enough when you have all the information, but trying to establish the facts when reports are incomplete is next to impossible. To standardize data collection, most departments use a general complaint form to record information.

The booklet entitled *Procedures To Investigate Foodborne Illness,* published by IAMFES, the International Association Of Milk, Food and Environmental Sanitarians, shows an example of a general illness complaint form.

Categories in illness complaint form include the following:

- identification
- demographics
- clinical information

- exposure information
- reporter information

Whether you are using a paper copy of the illness complaint form or computer program, the form can be broken down into categories such as personal identification, demographic, clinical, and exposure information.

Identification

Start with basic identification information on the caller such as name, address, and phone number for home and work. Additional information may be needed from the caller as the investigation progresses. Plan a follow-up contact. If the caller wants to remain anonymous, tell them it may be difficult to keep in touch as the investigation continues. Attempt to identify additional cases. Ask if the caller knows of anyone else who is ill. If you suspect an outbreak, get information about the event, the exposure, the number affected. Ask for the names of both ill and well individuals who attended the event, and be sure to get telephone numbers of the persons affected. The goal of a case investigation is to get as much relevant information as possible. Timing is important. Each bit of information may lead to more cases or contacts. If you can't get all the information on the first contact, then get the basics on the caller, the illness, and the food operation.

Demographics

Knowing demographic characteristics allows you to describe the people affected by an outbreak. Some demographic characteristics include, for example, age, gender, occupation, race, and education.

Clinical Information

Take time to talk with the caller about their clinical signs and symptoms. Discuss initial impressions and find out how the caller learned about the illness, possible diagnosis and any medical assistance sought, specific symptoms, time of onset, duration of illness. Have they seen a doctor? If yes, who? What was the diagnosis? Were they hospitalized? What tests or samples were done? What were the results? Was any treatment provided? Also ask about chronic conditions, allergies, or medications that could mimic the symptoms of foodborne illness.

Find out if samples were submitted for analysis and if results are available. If samples have not been submitted, you may want to request a sample. A follow-up call to the physician can confirm the information you have, and you may be able to obtain the results of any pending tests.

Let the caller tell you what they believe happened. Then work to obtain the full history. When you're busy, you may not want to spend a lot of time on a single case that could be a dead-end. But you never know. The single report could be the tip of an iceberg. If a second case is identified and verified, you won't want to

waste time re-interviewing the initial caller. So when a complaint is received, get as much information as possible up front. Remember, the better the initial information, the more likely your chances of early identification of an outbreak.

Exposure

For a variety of reasons, when foodborne disease is suspected, information of foods consumed in the 72 hours prior to the onset of symptoms is requested. People have trouble remembering what they have eaten. It's not easy to obtain a food history, but the details contained in the food history are necessary for identifying potential exposures. The 72-hour time frame is used because recall gets very unreliable for foods consumed more than two to three days before an interview. Most people lead fairly routine lives, and a five- to seven-day food history could capture virtually everything they ever ate, increasing the difficulty in implicating a food vehicle. Also, the incubation period for many foodborne pathogens is 72-hours or less. Of course, there are exceptions. The incubation period for *Hepatitis-A* is 15 to 50 days; *E. coli* O157:H7 has an incubation of 3 to 8 days; and *Trichinosis* has an incubation range of 5 to 45 days.

The 72-hour food history should include all meals, snacks, and beverages, including water and ice eaten at commercial operations, as well as in the home. Find out where the foods came from. Were meals prepared on-site or catered, and did food come from outside sources? Ask if they noticed anything unusual about the foods, such as, off taste, texture, color, or odor. Find out if hot foods appeared fully cooked and were served hot and if cold foods were cold. If there is leftover food, give instructions for labeling and storing the food before it is taken to the lab for analysis.

When individuals can't recall the specific foods they ate, see if you can help them out: Ask about their food preferences, what they usually eat and where they have eaten lately. If you can't obtain a full 72-hour history, then try to obtain a facility-specific history. Ask about meals eaten out and then ask about meals eaten at home. A good wrap-up question could be "Is there any other information that may be relevant that you could provide?" Make sure that the caller knows that you may be calling them back if you need additional information. Also ask them to call you if they remember any other information about the event.

Many callers will attribute their illness to the last place they ate and may have already decided what food made them ill. We often assume that illnesses are foodborne in nature, but we need to keep an open mind to the idea that other factors may play a role. You don't want to put all your eggs in one basket. For example: there was a Salmonellosis outbreak, but the investigation did not reveal any food associations. The EPI evidence showed the common item among the cases was marijuana. The lab found the same type of *Salmonella* in both the marijuana and cases. So remember, the source of illness may not be food-related. Ask the caller if they have done anything unique or different recently. Ask about domestic or international travel and whether they've had contact with ill persons or with animals.

When an illness complaint is received, examine the symptoms, onset times, and the 72-hour food history. Use the food history to see what was consumed prior to onset of symptoms. Try to match up foods, incubation times, and symptoms that could be associated with the possible pathogens. Of course, you should go through this exercise when the caller reports a self-diagnosis and the pathogen and source are unknown. But even if you do have a medical diagnosis with a known pathogen and possible source, play "devil's advocate" and review the data for consistency. (Editor's comment: Make a distinction between an investigation that supports the first plausible explanation you think of and a legitimate investigation. It is bad form to identify a food vehicle and cause of illness based on incubation period and symptoms and then to design an investigation to prove the association.)

Symptoms One Hour After Eating

For example, say the illness report concerns a person complaining of tingling and burning sensations around the mouth, facial flushing, dizziness, headache, and vomiting about one hour after consuming a large tuna steak. Is this complaint plausible? A review of reference materials would indicate they are plausible. These symptoms and onset time suggests a toxin or chemical poisoning. Specifically, the symptoms and onset are similar to that of scombroid-type poisoning, where histidine is converted to histamine. That type of poisoning is most often associated with fish in the Scombroid family, of which tuna is a member. **As a general rule, symptoms of chemical and toxin poisonings occur within one hour of ingestion**. But keep in mind that some toxins and poisons can have a longer incubation period.

Nausea and Vomiting Less than Six Hours After Eating

Here's another situation. Say the illness report concerns a person complaining of only nausea and vomiting. You have a 72-hour food history. What part of the food history would you concentrate on? Look at what was consumed in the six hours prior to onset. **Pathogens such as *Staphylococcus* aureus or the emetic form of *Bacillus* cereus would be good candidates for this time frame.**

Cramps and Diarrhea, Six to 20 Hours After Eating

Say the illness report concerns a person complaining of only cramps and diarrhea. What incubation times would you expect? In general, for cramps and diarrhea only, look at what was consumed between six and 20 hours prior to symptom onset**. Possible suspects may be *Clostridium* perfringens or the diarrhetic form of *Bacillus* cereus**. If fever and diarrhea are symptoms, consider a possible infection. Illness with fever generally indicates an infection rather than intoxication.

Diarrhea and Fever, 12 to 72 Hours After Eating

Pathogens that infect typically require a longer incubation time to allow the organism to multiply in the body. Look at foods consumed about 12 to 72 hours

prior to onset. Keep in mind that these are general rules. They give us a place to start; they're not absolutes.

Decide whether further investigation of a complaint is warranted.

There's a lot to consider here, including the number of cases, the agent, the severity of illness, and how long ago the illness occurred, not to mention the department's policies, investigation criteria, and resources. Determining whether you actually have a foodborne illness outbreak and deciding when to initiate action can be challenging. If you' re investigating a serious illness, the investigation could begin based on a single report. But for a less-serious illness, follow-up may be postponed until additional reports are received. Analysis and interpretation of surveillance data can help identify potential problems. For example, if a decision to follow up is made based on analysis of log entries, the investigator should determine whether an increase has actually occurred and whether the increase can be linked to an obvious common exposure. Evaluate the data to ensure that there is a plausible basis for the potential association and verify the diagnosis. It may be necessary to find more cases, collect more data.

Verify the Complaint

To verify a complaint, let your fingers do the walking! If the report says they saw a physician, call the physician; diagnosis may have been made based on symptoms. If clinical specimens were submitted, check with the lab.

Here's an example of a problem resulting from not verifying the complaint (a generic story). A complaint was called in, foods, symptoms, incubation times; it looked like they had a "textbook" case of staph or emetic *Bacillus* cereus. Two were hospitalized. The investigators rushed out to investigate. A few hours later at the facility, they received a call from the office telling them that those two at the hospital didn't exist and the caller's phone number was disconnected. He said that they felt set up. In their discussions with the facility owner, they were told that there was some guy in the previous night who ate $20 worth of food. After finishing it, he said he didn't like the food and shouldn't have to pay for it. I guess he ended up having to pay for the meal and thought it would be a great prank to phone in a complaint the next morning. If only they had made a phone call to verify before going out to investigate! Verify before you act.

Surveillance

Public health surveillance is a systematic way to keep your finger on the pulse of the community. To detect disease patterns and to control the spread of disease in the community, you must become familiar with your surveillance data. Data must be analyzed to identify individuals with similar symptoms or the same diagnosis. The description of community health that emerges from surveillance data should be communicated to health professionals on an ongoing basis.

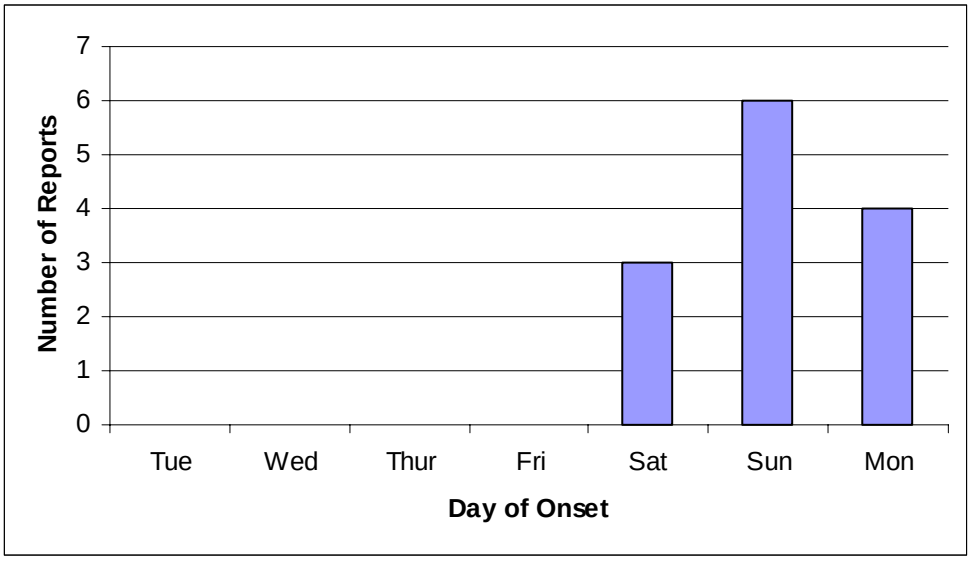
Associations by Time, Place, and Person

Case report data from the surveillance log can be organized with respect to time, place, and person to find possible associations among cases with the same diagnosis or similar symptoms. For example, when you review reports, trust that "deja-vu" feeling. If individuals experience similar symptoms and onset times, they may have a common association with a particular place or event.

If there appears to be a meal in common that is associated with the illnesses, then the time between ingestion of the agent and the onset time provides the incubation period. The incubation period and symptoms are helpful clues in determining which diseases "could be" or "definitely are not" involved with the illness. Incubation times will vary among cases. That's why incubation periods are given over a range of time. The time frame the investigation team is concerned with is related to the suspected agent's incubation time. For example, let's say several reports of confirmed Salmonellosis were received over the last week and onsets for these cases occurred within 60 hours of each other. It is possible that these cases could share a common source of exposure, because all the onsets fall within one incubation period for Salmonella, typically 12 to 72 hours.

Associations by Time

When illness complaints are organized by time, the data may be displayed on a graph. Graphs show visually the relative size and trend of the problem and can be constructed to show daily or seasonal trends or time intervals that span several years. Graphing the data a few different ways will help you decide on the most appropriate and revealing time interval to use. Graphs are very useful for showing past trends and for predicting future trends. They can also provide insights into what may have caused the problem.



Reports of diarrhea onset by day of week in college students, November 3-9

Let's say several reports for a cluster of suspected Shigella illnesses were received, and the diarrhea onset times for the ill college students were graphed. The illnesses occurred Saturday, Sunday, and Monday. The typical incubation period for Shigella is between 24 and 72 hours. It is possible that the students shared a common source of exposure, as all of the cases fall within one incubation period. So if they ate any meals together Friday, one or more of the meals could be associated with the illnesses.

Association by Place

Reviewing illness reports with the same diagnosis or similar symptoms and onset times may show a common association with a particular place or event. Association by place refers to the attributes or factors that describe the environment in which the disease occurred, such as geographic location, county, town, food-service facility, business, residence, social event, purchasing food from the same place, or consumption of a specific brand of food. The data can be mapped, graphed, or tabulated to help you gain insight into the geographic extent of the problem.

Analyzing data by place may help you identify the most likely pathogen and may give you insight as to how illness could be spread. If the illness is associated with a particular place, then it's a safe place to start investigating to see whether the risk factors of illness are or were present.

If the students ate a meal together, the place associated with the illness can be determined as well. However, the only information the team may know about the source of illness is that cases are currently occurring over a broad locality such as the state, county, township, or college campus.

Associations by Person

Person associations refers the characteristics of ill individuals with similar symptoms or diagnoses of those who were exposed to the agent or suspect agent. Some categories used to group data by person are age group, gender, occupation, immune status, affiliations or group membership, extracurricular activities, or any other unique characteristic. It turns out that personal characteristics sometimes can be used to predict who is at greatest risk of becoming ill from a particular pathogen. You may have to group your data several different ways before deciding on the most appropriate and revealing person-category to use to get a better picture of the situation.

There are times when an outbreak may not be limited to a particular group of people. For example, the students who reported diarrhea may have eaten off campus, and possibly there are other nonstudents out there who may have also become ill. Once the associations for time, place, and person are known, control and prevention methods can be implemented.

Refer the example of the surveillance log. Remember, we had three entries of *Hepatitis-A* in two weeks with all having some association with the Hillside day-

care center. Here, the association by place is easily identified, but sometimes the cases must be interviewed before time, place, and person associations can be identified. The question, “What is the correlation between *Hepatitis-A* and the day care?” can be answered only with follow-up.

Questions to Be Answered

These questions need to be answered: Who? What Disease? Where? When? Why? and How Many? to explain the illnesses and also Who else is at risk?

Who is Ill?

Three cases: a four-year-old boy, a four-year-old girl, and the day-care center cook -- a 42-year-old female.

What’s the Disease or Agent?

The diagnoses were reported as *Hepatitis-A*.

Example of a Surveillance Log, Week 2

Case #	Reported by	Time of report	Signs & symptoms, and lab results	Time of onset	Case's name, address, occupation & telephone #	Age	Sex	Possible sources of exposure, per reporting individual	Other similar cases
11	W. Hogan, MD 297-6834	1-17 3 p.m.	Hepatitis A Dark urine, clay colored stool, tired, jaundice	1-12	Billy Michaels 4211 Maple Drive	4	M	Unknown - attends Hillside Day Care Center	X
12	G.M. Miller, MD 458-2211	1-18 10:30 am	Meningacaccal Meningitis - headache, pain in legs, chills, fever, vomiting	1-14 5 p.m.	Anna Wilson Bay City	17	F	Unknown	
13	Anna Lewis 543-7918	1-18 10:45 am	Dog bite – puncture wound on left leg	1-18 am	Bobby Lewis 950 Rancho 543-7918	8	M	Dog's owner - Fred Allgood 695 E Rancho 543-8842	
14	W. Hogan, MD 297-6834	1-18 11:45 am	Hepatitis A Vomiting, fever, dark urine, jaundice	12-31 7 p.m.	Idda May Jones 127 Hill Circle Cook at Hillside Day Care Center	42	F	Unknown - visited relative early in December	X
15	F. Diaz, MD 223-8846	1-18 2 p.m.	Measles, fever, rash	1-14 8 am	Joey Hernandez 72 Rancho Road 224-7713	3	M	Unknown - attends Hillside Day Care Center	
16	S. Menousek, MD 764-0241	1-18 2:45 p.m.	Hepatitis A	1-13	Susie Smith 238 Taft Street 448-7283	4	F	Unknown - attends Hillside Day Care Center	X
17	James, Mitchell, MD Brassfield Hospital 247-8900	1-18 3 p.m.	Post op., staphylococcal infection	5 cases since 1-1	5 cases - hospital has records		F	All are post op in general surgery wing	

Where Are Cases Occurring?

So far the only association for place is the Hillside Day Care.

When Did the Time of Onset for Each Report Take Place?

The four-year-old boy's time of onset was January 12; the young girl's was January 13; and the cook's was December 31.

Well, we know *Hepatitis-A* can be transmitted person-to-person or fecal-orally with food and water. The average incubation period is 28 to 30 days, with a range of 15 to 50 days. An infected person begins shedding the virus about half way through their incubation period and can continue for up to a week or more after onset. Based on onset times, it's conceivable that the cook may have been the source and food could be the vehicle of transmission. That sounds like a reasonable hypothesis and a good starting point for beginning an investigation. Once the associations for time, place, and person are known for a particular agent, control and prevention methods can be implemented.

So Who Is at Risk?

If Hillside Day Care is the actual source of exposure, then anyone attending the day care who has not already had the disease and all those not vaccinated against *Hepatitis-A* are at risk. Also, because secondary spread can occur with *Hepatitis-A*, anyone exposed to these cases, such as household contacts, could also be at risk too. Be on the lookout for more reports of *Hepatitis-A* as a result of secondary spread.

Remaining questions such as "How did the exposure occur?" and "Was Hillside Day Care the source of exposure?" can be answered only after follow up with these three cases and the day care center.

Taking Action

How do you know when you've reached a critical juncture to initiate action? The answer to that question is not straightforward. Some departments follow up every single foodborne illness complaint, while others may only follow up obvious outbreaks.

Begin by looking at the terms outbreak, cluster, and epidemic. They all refer to the frequency of a disease that is above background levels for an area or is above expected numbers over some time period. Typically the term cluster or outbreak is the preferred term over epidemic, because outbreak or cluster sound less provocative to the public.

Definition of Foodborne Illness Outbreak

The definition of a foodborne illness outbreak can be generally defined as "two or more people experiencing a similar illness resulting from the ingestion of a common food." The definition of an outbreak could also be expanded to specify that the foods are epidemiologically linked to the illnesses. But the epidemiological link won't be known until the investigation is well underway or completed.

However, that does not mean that a single case of suspected botulism, mushroom poisoning, ciguatera, paralytic shellfish poisoning, chemical or other toxin poisoning should not or could not be investigated. Many departments use this definition of an outbreak as a guide for developing their policies, but response to a situation also depends on the number of cases, the severity of the agent and how long ago illness occurred, as well as the department's resources.

Some jurisdictions require that more than two people meet the outbreak definition before starting an investigation while others will act on two, and some might even respond to a single report of illness. There is really no right answer when you are dealing with just a few illness reports. All food safety organizations should have or should develop policies for investigating foodborne illness. The important thing is to be flexible and not process-driven.

Decision to Follow Up

Many factors influence the decision to follow up. For example, is the affected population considered high-risk for exposure or serious illness? Are illnesses associated with the immunocompromised; for example, a nursing home or day-care center? Has anyone been hospitalized? What is the severity of the illness associated with the agent? Are the symptoms typical of foodborne illnesses, or are there neurological symptoms involved or bloody diarrhea? Remember, symptoms of foodborne illness can resemble underlying medical conditions, and because of the biological variability, everyone will not have exactly the same symptoms. Most infected people will have a similar range of symptoms, but some people may be asymptomatic (not show any symptoms). All of these factors can affect the timing and level of response.

Depending on the circumstances of the illness complaints, there may be several response options. Here are a few examples. A health department may receive a report from a doctor or lab regarding someone who works in food service who has been diagnosed with Salmonellosis, *Hepatitis-A*, or Shigellosis. Since an infected employee could be a potential for illness, sending an investigator to the facility and restricting the employee's activities or excluding them from work until they are no longer a health threat would be prudent.

Consider the situation in which the department receives a single illness complaint on a facility or one in which they may have received a string of sporadic complaints over the last few months. One option is to review the history of the food operation and send a sanitarian to investigate. The primary job of the

inspector is to ensure that the operator is in compliance with safe food-preparation procedures. In essence, if any problems with food preparation procedures are noted and corrected, then any additional illnesses would be prevented.

A problem with passive surveillance is that some claims of illness are reported late, sometimes weeks after the event and the trail has turned cold. People who were ill no longer have symptoms. They can't remember everything they ate, and food samples are no longer available. In a situation like this, the sanitarian or investigator can simply follow up at the facility to ensure that safe food practices are in place.

Another problem situation is trying to follow up on claims of illness when people are uncooperative. People contact you initially and report the illnesses. Then, when the investigation begins and you need more information such as a list of names, food histories, symptoms, or specimens, they are not interested in participating. In situations like this, when you do not have enough information, you can at least evaluate the facility's food-preparation procedures.

Sometimes it's easy to tell when you have an outbreak. The calls come from several people who are ill after eating at a wedding reception, or a hospital emergency room calls to say they have several people sick who all ate at the same restaurant. Even in this type of situation don't forget to consider associations between person, place, and time. Don't have tunnel vision. Leave the blinders to skittish horses! Cast a wide net initially to make sure you haven't missed anything. In a situation where you have ongoing illnesses and people may continue to be exposed to contaminated food, a rapid response is critical. Activate your outbreak team early in the process. Involve the epidemiologist, public health nurse, sanitarian, and laboratory personnel, and thoroughly investigate the event. Exactly what the level of response is depends on your department policies.

That's some good advice. There are a lot of factors to consider when determining how to respond to complaints of illness. And, of course, using good old common "horse sense" helps, too. Unfortunately, most of the time we don't have very good information to start with.

Once you believe that there is sufficient information to initiate a foodborne outbreak investigation, verify the existence of a group of possible related cases that may be linked by a common food. Verify the diagnosis and reevaluate the information. If the information seems reasonably sound, then contact the team leader or supervisor as applicable. Also, depending on the circumstances, notify other state or local health officials.

Once a decision has been made to investigate, the facts concerning time, person, and place associations should be shared with those conducting the investigation. The team member who has the role of the epidemiologist should begin developing an initial hypothesis and initial working case definition. The search to find additional cases should also begin. As the investigation expands, the various steps of the investigation can be done simultaneously by different members of the team. You know the investigation will involve interviewing, developing EPI data,

an environmental investigation, sample collection and analysis, and implementing control measures. Collect food and clinical samples early before potential samples are lost forever. Recognize that many of these steps just depend on the circumstances, and keep an open mind as you work through the investigation.

Use your investigative skills along with your understanding of the relationships between the agent, host, and environment for the known or suspect agents. Don't set out to just find a foodborne disease outbreak. The common exposure may be food, water, air, animals, or something in the environment. It's also possible that more than one pathogen may be involved.

Outbreak objectives:

- Gather data as fast as possible
- Define the problem
- Identify the agent
- Determine the cause or contributing factors
- Control the risk of secondary transmission
- Stop propagation of the agent
- Prevent recurrence

Remember, the objectives of the investigation are to gather data quickly, accurately define the problem, identify the agent, determine the cause or contributing factors, control the risk of transmission from person to person, stop further propagation of the agent, and prevent the situation from recurring, and you also want to learn from the experience. Do not forget an important field axiom, "Get it while you can," before potential food and clinical samples are lost forever.

At the start of an investigation, there is a lot of missing information concerning the who, what, where, when, and why of the outbreak. One of the first steps is to organize what is known and develop the initial hypothesis. (Editor's note: This is probably true for the majority of simple outbreak investigations. However, in more complex situations, neglecting to do detailed hypothesis-generating interviews and not consulting with experts may lead to unsuccessful outcomes.) A hypothesis is a theory or speculation that is formulated in an attempt to explain how an event occurred. Often, cursory observations can appear to be facts, when they may or may not be true.

Usually the preliminary information is sketchy, but you have to start somewhere and have a rough idea as to where you're trying to go. The team needs some leads to follow. Whether the illness complaint is a self-diagnosis or medical diagnosis, examine the symptoms, onset times and 72-hour food history. Look back at what was consumed prior to onset, and try to match up possible incubation times, symptoms, and foods with possible agents and the illness. The

first hypothesis may need to be broad in scope and cover all the plausible "could-be's." Obviously, there will be many missing pieces at this point.

The hypothesis should address, as well as possible with the limited information, the agent, source, mode of transmission, exposure periods, and possible contributing factors that caused the illness. As the investigation progresses, expect to update hypotheses as more facts are uncovered and the set of possibilities diminishes as previous "could-be's" are eliminated or modified. Keep in mind that it's possible for more than one pathogen, meal, menu item, or other environmental exposure to be implicated.

Example of Initial Hypothesis

Consider the scenario in which complaints are received on four individuals with symptoms of diarrhea, and two of them also had abdominal cramps. Food histories were completed on all four, and the only time, place, and person associations were eating at Albee-Jon's Restaurant on March 1. Three of the individuals had lunch, and the other had dinner there. If these meals at Albee-Jon's Restaurant were associated with the illness, then based on onset times, possible incubation periods are ranging from 11 to 20 hours. With this sketchy outline of information, we could develop an initial hypothesis of: Individuals eating at Albee-Jon's Restaurant on March 1 experienced diarrhea or diarrhea with abdominal cramps within 20 hours. Possible agents could be *Clostridium* perfringens or *Bacillus* cereus. The hypothesis was intentionally kept broad by including all meals served at Albee-Jon's on March 1, not just lunch and dinner. Now, the team has time, place, and person associations and an initial list of foods and possible agents to begin the investigation. The team should keep in mind that the illness may not be foodborne, and even if it is foodborne, the pathogens may not be C. perfringens or B. cereus.

Case Definition Exercise

Let's continue with the case definition. Developing a case definition is done to identify those who are thought to be suffering from the same illness and to specify the criteria to classify exposed individuals as either a case or noncase. Persons who are ill but do not meet the case definition are considered to be noncases.

The case definition is developed to place boundaries on **who** will be considered a case in the outbreak by specifying a diagnosis or clinical signs and symptoms, and restricting time, place, and person associations, so the investigation is not overwhelmed with unrelated illnesses.

Developing a case definition is not easy. The range of symptoms for a specific foodborne illness can mimic or resemble other foodborne diseases, or other underlying medical conditions such as Crohn's disease or irritable-bowel syndrome. Remember, individuals with the same disease will not experience exactly the same symptoms, because of the biological variability, but will undergo a similar range of symptoms. Usually infected people are symptomatic. Occasionally, reports may be received from a physician or lab regarding

asymptomatic cases. These are individuals who do not show signs of illness but maybe shedding the agent in their stool. For example, you may hear of asymptomatic cases of *Hepatitis-A* or *Salmonella*.

Usually, when the initial case definition is written, little is known for sure. There may not be a clear picture of what's occurring, and some of the data may be contrary, requiring it to be reviewed more carefully. At this point, the initial case definition needs to be broad enough to capture most of the ill, so it is less restrictive.

Since a case may not exhibit all of the symptoms associated with an illness; some flexibility in clinical parameters for the agent should be included in the case definition, such as two or more of the following symptoms. Consider primary or predominant symptoms in the initial case definition, such as jaundice, diarrhea, or vomiting, as opposed to more general, nonspecific symptoms such as headache, chills, malaise, or nausea. Symptoms such as fever and diarrhea may need to be further defined, such as fever greater than 101 and diarrhea being three or more loose, watery stools in a 24-hour period. (Editor's note: This case definition excludes ill persons who did not eat at Albee-Jon's. If the restaurant association is false, the investigation may lead to an incorrect conclusion, unless the case definition was revised.)

The working case definition is usually refined as the investigation progresses. At the conclusion of the investigation, the final case definition is developed and becomes a part of the final report. For an example of an initial working case definition, let's go back to the scenario at Albee-Jon's Restaurant. Remember, four complaints were received: all had diarrhea, and two of them also had abdominal cramps. If eating at Albee-Jon's on March 1 was the cause, then possible incubation periods range from 11 to 20 hours. The case definition could say that ill individuals are those who ate at the restaurant on March 1 and developed diarrhea alone or diarrhea with abdominal cramps. Diarrhea is defined as three or more loose stools in 24 hours. If an illness complaint was received from an individual who ate at Albee-Jon's on March 1 and complained of vomiting and nausea four hours after eating lunch, the person would not be considered a case. At this point, this person is considered to be a well person and would be used as a well person in the initial statistical testing. Depending on how the case definition changes later on, this person might be considered as an ill person.

Expanding the Investigation

Objectives

Upon completion of this module, participants will be able to:

- Conduct an effective interview.
- Define a case and locate additional cases.
- Develop an effective questionnaire.
- Understand the significance of, and utilize data from, an attack rate table.
- Interact productively with the news media.

We've reviewed a surveillance log, looked for patterns to identify potential outbreaks, and discussed illness complaints and criteria for initiating a foodborne illness investigation. Once we identify an outbreak, we will need more information to prevent the further spread of the disease. It's important to act quickly. The investigation team needs to meet and discuss what is known about foods, symptoms, the diagnosis, incubation times, time-place-person associations, and means of transmission. Developing an initial hypothesis and case definition will provide focus and direction to the investigation. It is important to keep an open mind, be prepared for the unexpected, and keep the team members informed as they proceed with the investigation. No two foodborne illness outbreaks are the same and how the team proceeds will depend on the circumstances.

As the investigation expands, several tasks will be in process simultaneously as the three legs of the team, EPI, LAB, and Environmental, proceed with their portions of the investigation. We'll talk about the EPI side of the investigation first. Then, in upcoming modules, we'll pick up the environmental and laboratory sides of the investigation. In this module we'll discuss interviewing, case findings, updating the hypothesis and case definition, the outbreak-specific questionnaire, data organization, control measures, and the news media. Since most of our information is derived from questioning, let's begin by talking about interviewing techniques.

Interview Techniques

This is the part of the investigation where you need to dust off your people skills. The better your interviewing skills are, the more you'll learn about an event. And

the more accurate the information you collect, the better you'll be able to evaluate your hypothesis. An interview is a directed, definite, and purposeful "conversation" that involves more than just the words that are spoken. You must interpret what people say, the way they say it, their gestures, posture, facial expressions, eye contact, and other nonverbal cues. A good interviewer is also a good listener. Before you pick up the phone or walk into an establishment to begin an interview, think about your objectives and what you want to accomplish. Why are you doing this interview? Whom will you be interviewing? What is the person's age, gender, background, and occupation? Are they potentially responsible for the outbreak, angry about becoming ill, or confused about their involvement in an investigation of illness that appears not to involve them? What other characteristics will help you gather information?

For the most part, you'll need to gather information from ills and wells, and those involved with food preparation. One of the tough things about gathering information is it's not a nine-to-five business. You'll probably be working around a lot of different schedules: the owner of an establishment, cooks, kitchen crew, wait staff, people at the function, people who ate the food and those who didn't as well. Trying to find patrons is often very difficult. You may have to call them at home, in the evening or on the weekend. Given the many priorities you must satisfy, schedule interviews for times when they are likely to yield the best results. Whenever possible, make appointments and be punctual. Make it convenient for the person you're interviewing, so they're comfortable and more willing to cooperate. Remember, unlike a facility operator, the public is not obligated to communicate with you. If the time you've set aside is not convenient, try to reschedule.

Your mission is to gather information on the source of the illness and means of transmission. You want the cooperation of the people involved, so begin interviews by letting people know that you're a professional, and your job is to gather information. Remember that the situation may be threatening to them. Conducting the interview in a sensitive manner will help people feel comfortable. If you're not sympathetic to the feelings of others, they may react in a way that limits the free flow of information. Giving someone "the third degree" may not give you the results you need. And privacy is important too. Think about the person's feelings when you select your interview site. You want to avoid distractions, and some of the information may not be for everyone's ears. Most people would prefer not to tell the world about the diarrhea they had, or discuss other symptoms "in public." Perhaps, if you interview a patron or an employee in private, you'll get a more accurate picture of what happened.

Begin your interview with something like "There's been reports of possible foodborne illness and we're investigating to find out what happened." Right away people will want to know more about the investigation. Tell them you're just collecting information right now, talking to those who allegedly were exposed, and those who were involved in preparing the food. Your behavior will show your objectivity. If someone is hesitant about giving you information, tell them the purpose of the interview as clearly as you can and encourage their cooperation.

Many times both patrons and facility employees will also try to solve the case. Remember reputations may be at stake. A restaurant owner may be afraid he was at fault. A victim may want to know how you got their name. Go ahead and tell them. Be as open and honest as possible without divulging confidential information. As you begin the interview, establish rapport with the person. Try to establish mutual confidence and an understanding atmosphere so that the individual won't be afraid to answer openly. Greet the person with respect and introduce yourself, including your name, position, and department. Take time to explain the purpose of the interview and how it relates to the person's needs. If you feel at ease, then they're more likely to feel that way too. Allow a little time for the person to become accustomed to you and the situation. Remember to speak in terms they can understand. If the person can't remember something, ask them to think what else they were doing during the time period, to help them jog their memory.

Questioning is an art. Direct your questions so your goals for the interview will be met. Open-ended, non-directed questions encourage a person to use their own words to describe their experience. This approach, however, may be difficult, especially when you want the answer quickly. So ease into the interview. Start with a few directed questions like: "What is your name? Your address? Occupation?." Then go into open-ended questions. Here are several examples of open-ended questions, followed with close-ended questions. To verify the exposure, ask: "What were the foods that you ate?" Then follow up with: "Did you consume any other foods or drinks?" You might also ask: "After the event, how did you feel? Were you ill?" Let the person answer in their own words, then follow up with directed questions to fill in the gaps. A drawback with using only open-ended questions is that they tend to be more difficult to analyze statistically than yes-no questions. So fill in any voids with direct questions.

Closed-ended questions usually have just one answer option. Some examples are: "How many stools did you have in the last 24 hours? Was the diarrhea watery? What was your temperature? Did you use a thermometer?" If you're in too much of a hurry to complete the interview, you may be tempted to be too direct. Avoid leading statements like these: "I have a list of all the items that were served there that day. I'm going to read this list to you, and you tell me whether you ate these foods: yes or no.". When you interview a person in this manner, they are not likely to volunteer information that could be important.

Closed-ended questions can be restrictive and leading. For the most accurate data, let the interviewee tell their story. Think before you ask a question! Speak at the level of the person you are interviewing. Make eye contact when you're talking. If a response does not address what you're looking for, find another way to ask the question. Repeat the question and answer to be sure you both agree on what was said. Keep in mind that people may not admit to the truth for a variety of reasons and they may be afraid of losing their jobs. If they believe you will protect their identity, they are more likely to be truthful.

We all have a tendency to be so focused that sometimes we don't realize where other people are coming from, how they are going to react, or what's at stake for them. It helps to ask questions while being sensitive to "signals" from your interviewee. Usually, people want to cooperate. They're willing to work with you. But every once in a while someone may be trying to work against you. Learn how to handle these situations as part of your preparation. If you have not had conflict resolution training, make that a part of your professional development plan.

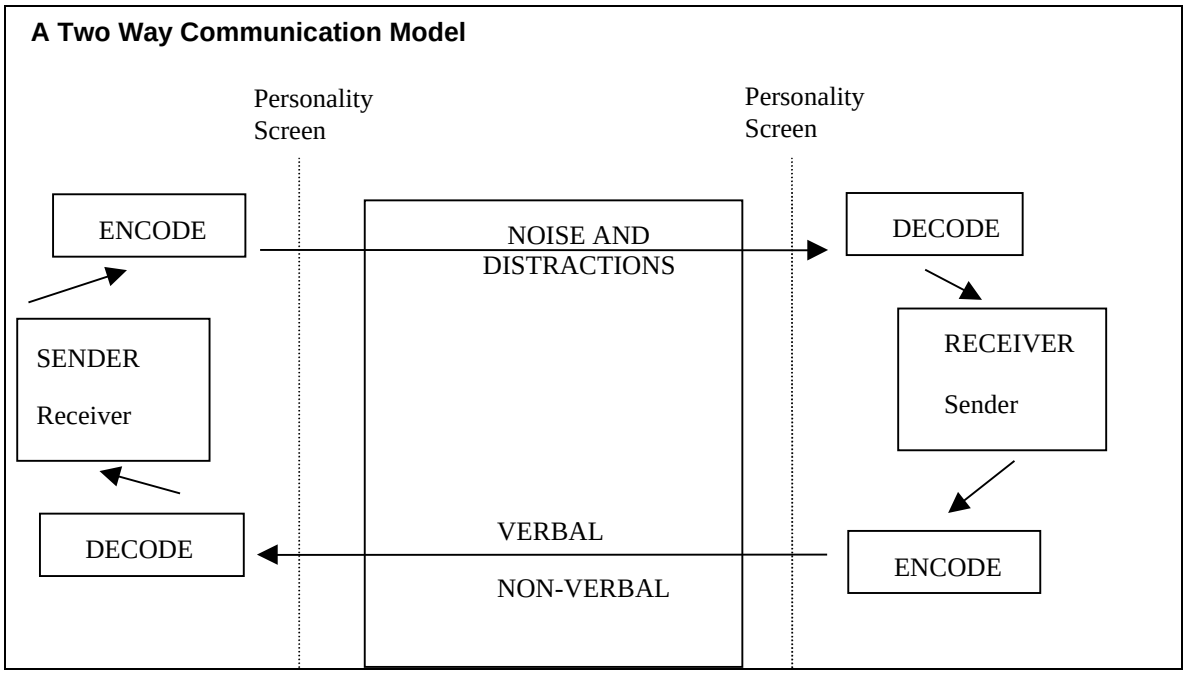
You should know your own style of interviewing. We all have different ways of doing things. Some people come on strong. Others are more passive. Also be aware of preconceived opinions you may be bringing to your interviews. For example, if you begin an interview with the opinion that this outbreak is due to chicken and all your questions are about chicken, then your own bias affects your result.

When you begin, explain the purpose of your interview in terms of your goals. (Editor's note: Be careful to avoid leading people to provide answers they believe you want to hear, rather than accurate and truthful answers.) Without a common point of departure, responses may not be as helpful. Be honest about why you're conducting an investigation. Ask for their help. Tell them you really need their input to make this a complete investigation. How the questions are asked and the order of questions can also affect the answers you get. And watch out for something called recall bias. Memories are not perfect. People may say they ate something that they didn't because they always eat that item. Or they may flat out forget eating a particular food item. Recall bias is almost always a factor in an outbreak investigation.

Be sure you don't influence your interview by the way you ask questions. Avoid leading questions or "double barrel" questions such as, "Did you prepare the chicken on this cutting board?" This question has two parts: Did you prepare the chicken? And did you prepare it on this cutting board? It's a bit difficult for someone to effectively answer two questions with one yes or no response. Another example of a double barrel question is: "Did you cook it and measure the temperature?" That question assumes that they indeed take product temperatures. Instead of assuming, ask how they know when it's done. Remember that the goal is to get the facts as they occurred without implying a particular response. Also use appropriate language, format, and terms for the person with whom you're talking. You may be talking to physicians at some point, cases and controls at another time, and later to kitchen workers.

Your rate of speech and tone may affect the interview. Remember our little role-play at the beginning of this section: "Were you there or not? Did you eat there or not? Did you eat this? The others said you did! What do you mean, you don't remember?" You have to let the interviewee tell their story. As we said before, avoid the third degree. Be alert to verbal and nonverbal feedback. Watch for body language, eye contact, signs of stress in the voice, and body posture. If signs indicate stress or uneasiness, adjust your approach and try to regain a comfort level with the person.

A Two Way Communication Model



Two-way communication is important. Remember the last time you said something that seemed perfectly clear to you, but the answer you got back was totally off the mark? That's because the other person heard it and processed it differently than you intended. The connection isn't made because each of you is coming from different perspectives. This model shows the many roadblocks that can get in the way of good communication. Each of us filters or encodes-decodes information based on our personality, culture, and experience. As the verbal and nonverbal communication travels through all the noise and distractions, you decode what was said and process the message through your filter and encode a response back. To avoid misunderstandings, recap the conversation. Rephrase what you think they said or repeat what you heard. Say something like: "This is what I understood you to say. Am I right? Correct me if I'm wrong. I want to be accurate. Your information is important."

As you conclude the interview with an ill or well person or food employee, you'll want to review your notes or questionnaire to make sure you have what you need. If for some reason you can't complete the interview, make another appointment and leave your card. Provide your name and phone number and allow people to call you from the security of their own home. Invite the person to contact you if they think of anything else and be sure to thank them for their time.

The following tips for good listening are from: Eastwood Atwater, 1981. I Hear You. Prentice Hall, Englewood Cliff, NJ. In: Dealing with the Press: Newspaper, TV, and Radio. FDA/STB, Handout 12-1-95

Do: Become aware of your own listening habits.

What are your strong points? What are your faults? Do you judge people too quickly? Do you interrupt too often? Better awareness of your listening habits is the first stage in changing them.

Do: Share responsibility for communication.

It takes two to communicate--one to talk and one to listen--with each person alternating as the listener. When you are unclear about what a speaker is saying, it is your responsibility to let the speaker know this. You can ask for clarification or actively repeat what you heard. Then ask to be corrected.

Do: Be physically attentive.

Face the speaker. Maintain appropriate eye contact. Your posture and gestures should show that you are listening. Sit or stand at a comfortable distance to put you and the speaker at ease. Someone who is speaking wants an attentive, animated listener, not a stone wall.

Do: Concentrate on what the speaker is saying.

Don't let your thoughts wander. A physical or verbal response will probably help you concentrate on what the speaker is saying. Listen for the total meaning, feelings as well as content.

Do: Observe the speaker's nonverbal signals.

Watch facial expressions and eye contact with you as the listener. Listen to the speaker's tone of voice and rate of speech. Does the speaker's body language reinforce or contradict what they just said?

Do: Be accepting of the speaker.

An accepting attitude on the listener's part creates a supportive atmosphere for communication. The more they feel accepted, the more they let down their guard and express what they really want to say. Be understanding. Use active listening skills to discover how other people feel, and what they are really trying to say.

Do: Listen to yourself.

If you can recognize your own feelings in reaction to another's message, express those feelings. This "clears the air" and helps you to listen better. And finally:

Do: Take appropriate action.

People speak in order to get something tangible done--to obtain information, to change an opinion, to get something done. You'll show that you're listening by how you respond. Actions speak louder than words!

Here are a few pitfalls to avoid:

Don't confuse "not talking" with listening.

People who remain silent aren't necessarily listening. They may be preoccupied with their own thoughts. On the other hand, some people can talk a lot and still listen well.

Don't "fake" listening.

Whenever you try to "fake" listening, your disinterest inevitably shows in your facial expression or body language. Staring, yawning and checking one's watch can be dead giveaways.

Don't interrupt needlessly.

People in positions of power tend to interrupt more often than those not in power... sometimes without realizing it. If you must interrupt someone, try to follow with a "retrieval"--help the speaker to re-establish his or her train of thought.

Don't pass judgment too quickly.

Judgmental remarks invariably put others on the defensive. They serve as barriers to effective communication. After they tell you it tasted and smelled bad and they ate it anyway, don't let the look of astonishment show on your face.

Don't make arguing an "ego-trip."

Even if you argue only "mentally" with what the speaker is saying, you may stop listening and look forward to your turn to talk. If you start to argue verbally, you will be so preoccupied with justifying your own views that you won't hear the other's viewpoint. When you honestly disagree, listen carefully in order to understand what you are disagreeing with. Then state your point-of-view.

Don't ask too many questions.

Too many questions have a way of shifting control of the conversation to the listener, putting the speaker on the defensive.

Don't tell a speaker "I know exactly how you feel."

This remark serves more to justify your own efforts than to convince someone you are really listening. It is difficult to know just how another person feels. Such a remark is likely to distract the speaker from further efforts at self-expression, and may cast doubt on your own listening ability. It is more effective to demonstrate you have heard with an observation like "I sense that you are feeling disappointed," or "I get the impression you are angry about this." Also don't give advice unless it is requested.

Don't overreact to emotional words.

Be careful not to get so caught up in a speaker's feelings that you miss the content of the message. And also realize your own feelings can block hearing something you really need to hear.

We use interviewing and listening skills to collect data about the outbreak, to update the working case definition, to generate a hypothesis and to test the hypothesis. (Editor's note: Different interviewing techniques are appropriate when getting patient information from a physician, when getting hypothesis-generating information from ill persons and food workers, and when getting hypothesis testing information from cases and controls. An unskilled interviewer can eliminate the possibility of correctly understanding the causes of the outbreak.)

A hypothesis is a statement that can be tested and refuted. The initial hypothesis is developed to help organize our thinking about possible time-place-person associations, and to provide direction for the investigation. As the outbreak progresses the hypothesis will be refined periodically to incorporate more of what we have learned about the agent, source, means of transmission, and how the illnesses occurred. The hypothesis will undergo testing to determine how our beliefs and assumptions hold up under the scrutiny of data analysis. If analytic methods testing fail to support the current hypothesis, then generate a new hypothesis. You may need to narrow the focus of your investigation to ask more specific questions on exposure history. Also consider new vehicles and modes of transmission.

Previously we learned that the case definition includes time-place-person and clinical criteria that an individual must meet to be considered ill. As the investigation progresses, the case definition will usually be revised and victims will be re-evaluated to determine if they are still considered within the set of outbreak related ill persons. If ill individuals meet the current case definition, they are outbreak related. Re-evaluation of the case definition should be done prior to organizing data for analysis, so the findings will only contain outbreak related cases and will not be mixed with unrelated illnesses.

Standard Case Definitions

Standard case definitions for reporting specific illnesses have been developed by CDC, the Council of State and Territorial Epidemiologists, and the medical community, but the wording of these reporting definitions may not be the best for use during an investigation. A standard case definition focuses on the ailment itself and indicates how certain we are that the subject actually has the illness under study. Time-place-person associations are not included in the standard case definition. The definition only states how sure we are that an individual has a certain disease based on clinical criteria or lab results. The degree of certainty is classified as confirmed, presumptive, and suspect. Thus, every case is diagnosed consistently and without bias. When you have laboratory confirmation of the agent, then the case definition can be stated to reflect how sure you are that each person is a victim of a particular illness. A case can progress from a suspect case to a presumptive case to a confirmed case as laboratory work is initiated and completed.

These classifications are developed to assist us in the comparison of case data. Analysis can be conducted on confirmed cases, on confirmed and probable cases, or on all cases. Comparing results of analyses of confirmed cases with those of suspected cases may indicate the likelihood that suspects are truly part of the outbreak.

Confirmed Case

A confirmed case has the clinical signs and symptoms of the illness, and there is laboratory confirmation of the agent causing illness.

Probable Case

In general, a probable or presumptive case is defined as a person with clinical signs and symptoms of the illness for whom there is some laboratory evidence that is **suggestive** of the illness. For some pathogens, the presumptive classification is not relevant because the particular lab test does not yield suggestive results. Lab tests may only confirm the presence or absence of the agent.

Suspect Case

A suspect case has the clinical signs and symptoms of the illness in question. It **looks** like they have the illness, but there is **no** laboratory confirmation to support a diagnosis.

Case Finding

Now let's talk about case finding, which is the process of locating additional exposed people. Those exposed may be either "ill" or "well." One way to conduct case findings is to contact known victims and ask whom they ate with and if they know the names of others who attended the event. Another way is to obtain a banquet or a reservation list. For facilities that accept credit cards, it may be possible to get the names of the patrons from the credit card receipts. Depending on the circumstances, it may be helpful to contact other health agencies, emergency rooms, and local medical care providers to find additional ills. You can also review surveillance logs for reports that may be similar. New reports may be part of the original outbreak or may be the result of secondary spread.

Don't just focus on the ills. Without information on the wells there can't be any meaningful data analysis to characterize the event. The foods consumed by both the ill and well provide a comparison for possible foods and meals in common. Usually, not everyone that eats the implicated food becomes ill, and others who report that they did not eat that food may become ill. Also people can have medical conditions that resemble foodborne illness or they can have a sympathetic response. For example, someone vomiting may cause others nearby to vomit.

In the early stages of an outbreak, reports may be recorded on a general complaint form. Once enough is known about an outbreak, such as the facility, symptoms, exposure period, and so on, then an outbreak-specific questionnaire can be developed by the outbreak investigation team to help with case finding and organization of information. The outbreak specific questionnaire is customized to focus on the circumstances of a particular event. Many of the questions on this specific questionnaire for the ill and well individuals are direct as compared to open-ended questions you'd be asking employees about food preparation procedures. Getting information by asking detailed questions may be the only way to get accurate information. Once these questions are answered, you can take appropriate public health action.

Questionnaires

(Editor's note: This section on collecting information using a questionnaire is related to, but is different from, hypothesis-generation interviews. Once enough is known about an outbreak, such as the facility, symptoms, exposure period, and so on, then an outbreak-specific questionnaire can be developed by the outbreak investigation team to help with case finding and organization of information.)

The usual way to obtain information is to ask a simple, direct question. The direct approach works, but experience shows the question-answer process can become complicated when information about a group is required. Complications result from nonresponse to a question, deceptive answers, lack of knowledge, or refusal to discuss specific subjects. When it comes to conducting a survey, poor memory is one of the biggest problems, and the inability to assign causality is the biggest limitation.

Questionnaire (Example of data Categories)

Identification	ID, name, address, phone number
Demographic	age, sex, race, occupation
Clinical	signs and symptoms of illness
Risk	place, time, dates of food consumption, menu, onset and duration of illness
Reporter	who provided the case report

The formats of the general complaint form and the outbreak-specific questionnaire are similar; both usually include identification, demographic, clinical, risk, and reporter sections.

Outbreak questionnaires must be administered as early as possible in an outbreak investigation. Make the survey a priority; this may require working longer hours and evenings when people are available. If too much time passes, the answers to the questions may be less accurate and may prevent you from finding out what caused the outbreak.

Investigators must have realistic expectations and plan the questionnaire based on specific needs. Before the questionnaire is designed, determine the best way to contact the respondents, and decide whether the questionnaire will be conducted in person or self-administered. Try to make the task of responding as easy as possible. Instructions for answering questions should be clearly stated in typical everyday language. When possible, design the response format to be *yes, no,* and *don't remember,* so respondents won't guess if they can't remember. The questions should be short and to the point. The investigator must be sure the vocabulary, reading level, and use of jargon is appropriate for the situation.

Don't overestimate the respondents' level of sophistication. To avoid interpretation problems, use simple, as opposed to compound or complex, sentences that can be understood by the least sophisticated respondent. Keep the readability to

about the eighth-grade level. You can improve your questionnaire by asking colleagues to comment on questions, phrasing, and overall format. (Editor's note: This method for improving a questionnaire is not a reliable field-test for a survey instrument.) Questions that are too general, or ambiguous, or that are really multiple questions should be rewritten. Response bias, resulting from subjects answering in a systematic way, can be reduced by including both positively and negatively worded questions.

Some questions may tend to upset an interviewee. Try to place them toward the end of the questionnaire. Put informative or interesting questions first. Avoid leading questions, and take care to carefully word all questions, especially those that are sensitive or potentially offensive. Research has shown that asking for excess demographic data can cause the respondent to be distrustful. So, only request information that is essential, and consider moving requests for demographic information to the end of the survey.

If you don't have a complete menu, you risk missing the food item that is the vehicle of illness. People are more likely to remember the foods they ate if you jog their memory. List every food item so you minimize poor recall. Ask about snacks, desserts, produce, garnishes, and beverages, including ice and water. As appropriate, ask about foods normally eaten, buying habits, favorite restaurants, ethnic foods, shellfish, special events, travel, and water supplies. Sometimes including a calendar of the time period can help people to remember details.

Include questions that help you track laboratory specimens. For example, you might want to ask if a stool specimen was submitted; if not, ask if they would be willing to submit a sample. If the subject has leftover food, ask if they would they be willing to submit the food for analysis. Provide space on the questionnaire for recording leftover food samples. Look for clinical information. Provide space for the diagnosis, and the name, address, and phone number of the caregiver. Ask about prescription drugs and other medications. Provide space on the questionnaire to record symptoms such as temperatures, type of diarrhea, and number of stools they have daily.

Consider your case definition and list the symptoms normally associated with a known or suspect agent. Ask about the date and time of onset and duration. Consider listing a few symptoms that are not usually related to the problem under investigation. Victims are often eager to cooperate, and some will answer *yes* to every symptom listed. If a victim claims to have one of the distracter symptoms, you may have a potential credibility problem. (Editor's note: The outbreak team must decide whether this person will be included in the analysis.)

If the pathogen can be transmitted person-to-person, remember that exposed persons may be infectious and can expose others to the pathogen. Provide space on the questionnaire for names, addresses, and phone numbers of persons who are potential secondary contacts. You may need to discuss control measures for preventing secondary transmission with all persons who have been exposed.

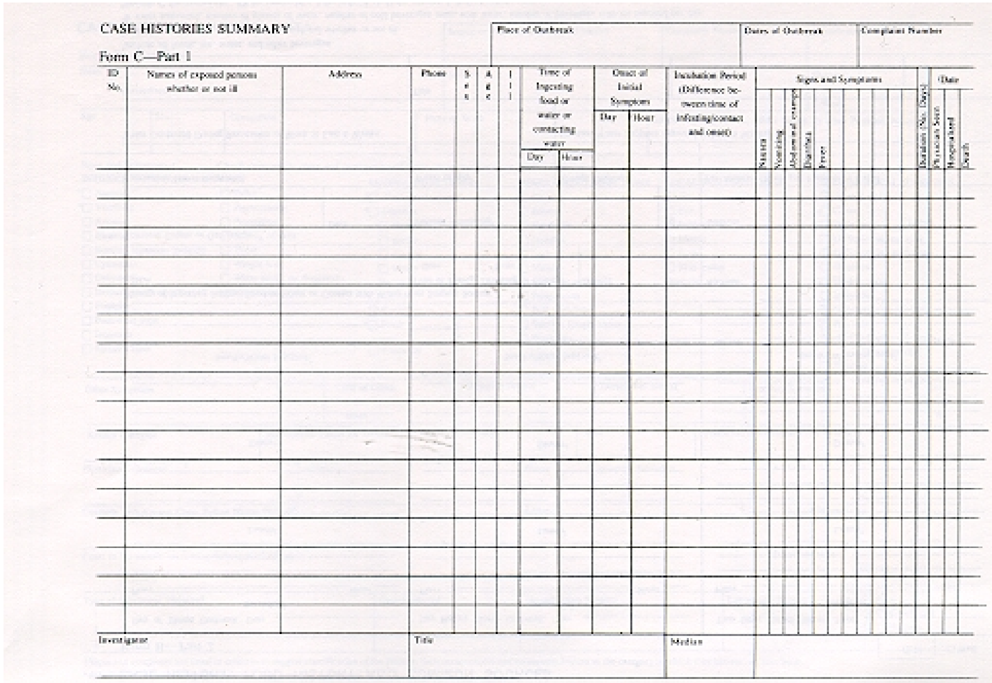
Use a standard, neutral, yes/no/don't remember format, and use it consistently. If your subject is unclear about a question, explain it to them. You might also get important new information by delving into the details of their answers.

Remember, even in a foodborne outbreak from a specific event, food can come from a variety of sources and suppliers. For example, if an outbreak occurs at a wedding, the caterer may supply the meal but not the cake. You would need to ask about the wedding cake on the questionnaire. Also, the event where the food was served might not be the only exposure. There may be multiple common events among groups such as a rehearsal dinner or a home gathering after the main reception.

Also consider the quantity of food eaten or served. For example, foods that were served to only a few people in a large outbreak may not be the vehicle of illness, unless there was cross-contamination. And foods served to everyone may not be the culprit if too few people became ill. People who eat more of a contaminated food item are more likely to become ill. It is also possible that someone may not have eaten enough of a contaminated food to become sick. In other words, it may depend on the dose of food a person consumes.

Line List

Now, as case information is collected, the names of ills and wells, dates, locations, symptoms, onsets, and foods consumed can be organized in a line list to make it easier to look for patterns in the data. A line list is a spreadsheet where columns represent variables and each row represents a person. The data can be sorted by age, sex, time of exposure, time of onset, and incubation period. The frequency of symptoms can be determined and data can be organized into various types of tables, graphs, and other ways to reveal associations. The following is an example of a line list.



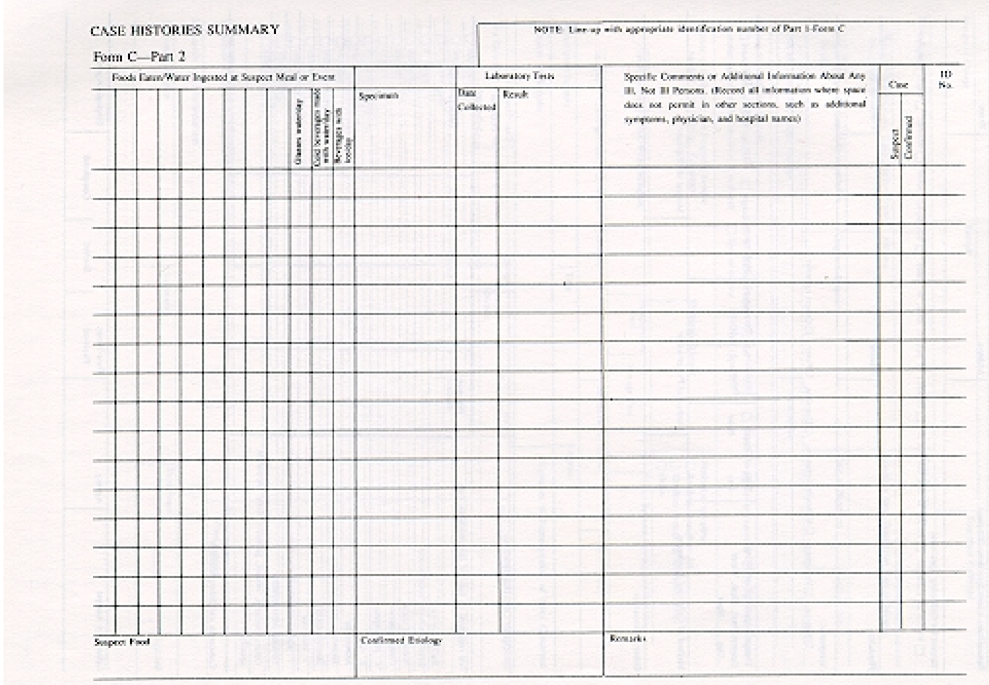
CASE HISTORIES SUMMARY

Form C—Part 1

Place of Outbreak | Dates of Outbreak | Complaint Number

ID No.	Names of exposed persons whether or not ill	Address	Phone	Sex	Age	Ill	Time of Ingesting food or water or contacting water: Day	Hour	Onset of Initial Symptoms: Day	Hour	Incubation Period (Difference between time of infesting/contact and onset)	Signs and Symptoms: Nausea	Vomiting	Abdominal cramps	Diarrhea	Fever	Duration (No. Days)	Date: Physician Seen	Hospitalized	Death

Investigator | Title | Median



CASE HISTORIES SUMMARY

Form C—Part 2

NOTE: Line-up with appropriate identification number of Part 1-Form C

Foods Eaten/Water Ingested at Suspect Meal or Event: Glasses water/day	Cold beverages made with water/day	Beverages with ice/day	Laboratory Tests: Specimen	Date Collected	Result	Specific Comments or Additional Information About Any Ill, Not Ill Persons. (Record all information where space does not permit in other sections, such as additional symptoms, physician, and hospital names)	Case: Suspect	Confirmed	ID No.

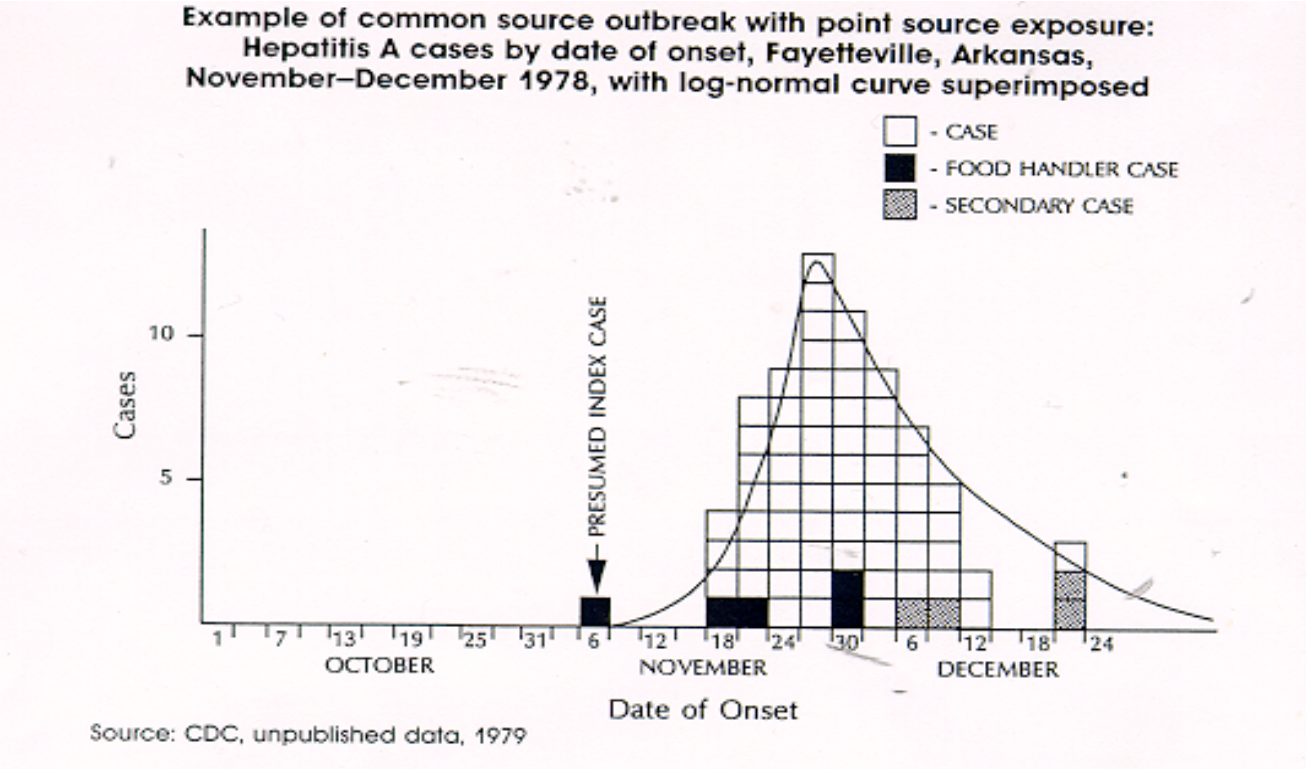
Suspect Food | Confirmed Etiology | Remarks

Reference: International Association of Milk, Food and Environmental Sanitarians, Inc. (IAMFES) "Procedures to Investigate Foodborne Illness" Fourth Edition, P.O. Box 701, Ames, Iowa 50010

Epidemic Curve

Another descriptive tool is the Epidemic Curve. From the line list, an epidemic curve can be developed to assist in determining plausible times of exposure and

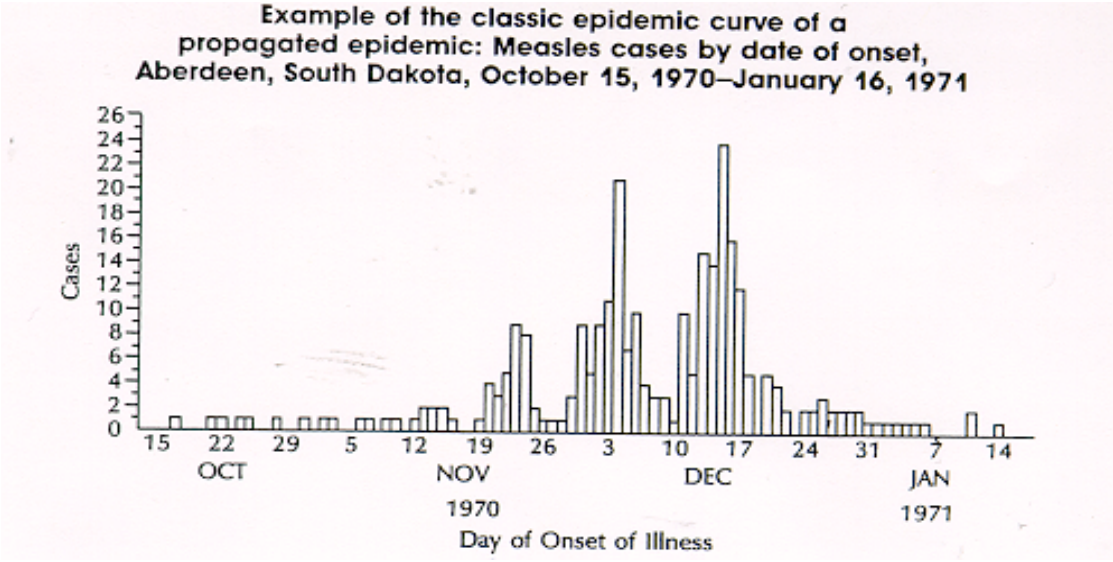
to visualize the time trend and size of the outbreak. The epi-curve is a histogram depicting each case's time of onset with the number of cases on the Y-axis and the date and/or time of onset on the X-axis. Time can be in hours or days or whatever the appropriate time period is, based upon the range of onset times in the line listing. Sometimes it's necessary to draw several epi-curves based on different time periods. Pick the epi-curve that best shows a pre-outbreak period, the initial case, and distributes the cases most clearly.



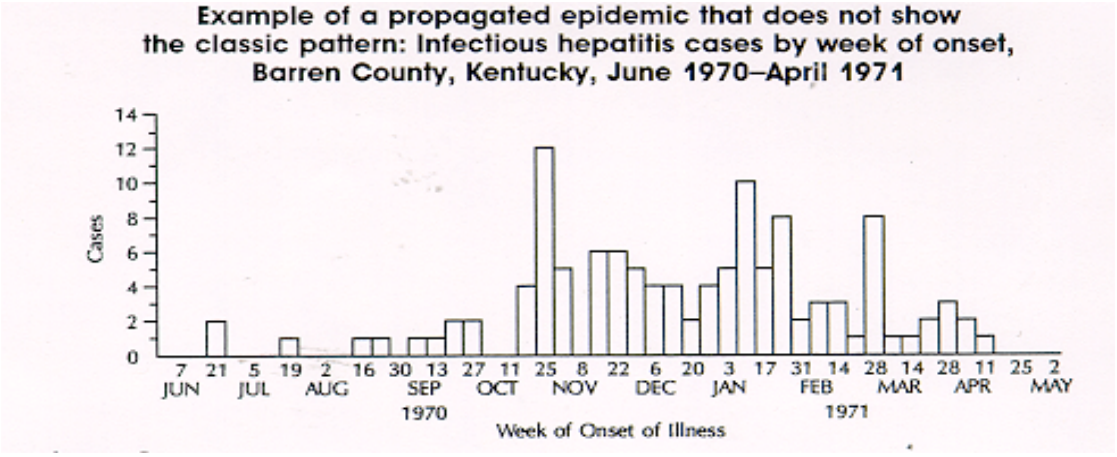
Reference: U.S. Center for Disease Control and Prevention, Principles of Epidemiology 2nd Ed. An Introduction to Applied Epidemiology and Bio Statistics, 1992, page 57.

Common Source Outbreaks

Epidemic curves can help show the type of outbreak that is occurring, such as a common source. Many foodborne outbreaks are common source outbreaks. The victims visited a common facility or event to ingest the agent. The source could be a food item that's distributed over multiple states and creates a multitude of outbreaks with a common source. Or, if the contaminated food is only served once at the facility or event and illness occurs, then the common source outbreak is also a single exposure event. If the vehicle was served multiple times, then it would be referred to as a common source, multiple exposure outbreak. This graph is an example of a common source *Hepatitis-A* outbreak. The peak of the outbreak should occur at approximately the mean or average incubation period for the agent, or in this example for *Hepatitis-A*, about 28 to 30 days after exposure.



Reference: U.S. Center for Disease Control and Prevention, Principles of Epidemiology 2nd Ed. An Introduction to Applied Epidemiology and Bio Statistics, 1992, page 58.

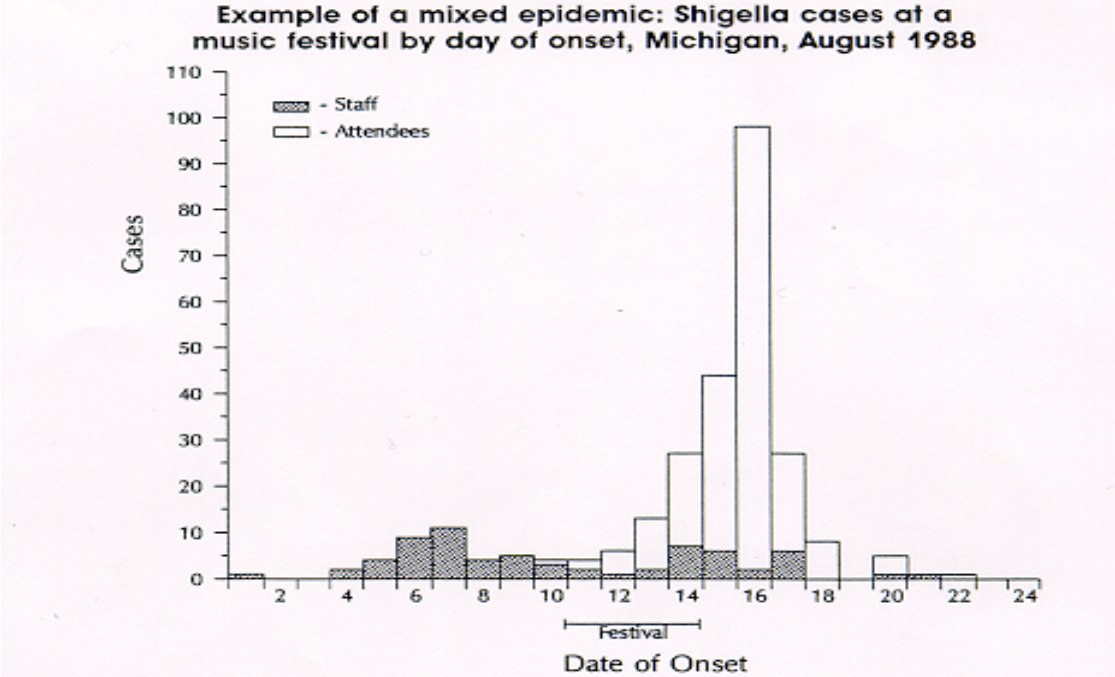


Reference: U.S. Center for Disease Control and Prevention, Principles of Epidemiology 2nd Ed. An Introduction to Applied Epidemiology and Bio Statistics, 1992, page 59.

Propagated Outbreaks

Propagated outbreaks result from those pathogens that can be spread person-to-person such as measles or chicken pox or such pathogens as *E. coli* O157:H7, *Shigella*, and *Hepatitis-A* that are also foodborne. (Editors note: Propagated outbreaks can also result from contaminated food being added to the next days' food.) The epidemic curve here shows a propagated outbreak for *Hepatitis-B*; it does not have a common source, but spreads gradually from person-to-person. There's not a relatively quick spike in the graph as there was in the last example of a common source. Cases increase and then decrease over a much longer period of time, spanning multiple incubation periods until control measures are implemented or the number of susceptible individuals is reduced to some threshold number. Some pathogens have multiple modes of transmission. They can spread via a vehicle such

as food and also spread person-to-person. Thus an epidemic can originate as a common source outbreak and continue in the community as a propagated outbreak.



Reference: U.S. Center for Disease Control and Prevention, Principles of Epidemiology 2nd Ed. An Introduction to Applied Epidemiology and Bio Statistics, 1992, page 59.

Mixed-Source Outbreaks

This combination is referred to as a mixed outbreak. From a foodborne perspective, mixed outbreaks originate from pathogens that can be transmitted via food and continue spread as person-to-person. This epidemic curve is a mixed outbreak of shigellosis revolving around a music festival. The shaded portions of the histogram represent the festival staff members and the nonshaded areas represent festival attendees. Remember, the incubation period for *Shigella* is usually around 24 to 72 hours. The first case occurred on day 1 with additional cases occurring prior to the festival. Approximately two days after the festival, the 16th day of the outbreak, the peak of the outbreak occurred with about 100 cases that day.

Attack Rate Table

Food history from the line list is then transferred to the attack rate table. An attack rate table is used to compare those who ate a specific food with those who did not eat the food. In general people who ate a contaminated food are the ones who become ill and people that didn't eat the contaminated food don't get sick. That's why it's important to interview people who didn't get sick. Consumption and illness data from the line-list is used to calculate the attack rates to determine which foods are most likely to be associated with an illness. A high attack rate

among persons who ate a specific food suggests that the food is associated with the illness. A low attack rate among persons who ate the food suggests the food is not associated with the illness.

The difference in attack rates is called the risk difference. The risk difference is the percent ill for those who ate a specific food minus the percent ill of those who did not eat the food. Here is an example:

Food	Those who ate the meal				Those who did not eat the meal			
	ILL	Well	Total	Attack Rate %	ILL	Well	Total	Attack Rate %
Bread	17	6	23	74%	9	7	16	56%

(17/23) x 100 = Attack rate #1 (9/16) x 100 = Attack rate #2
Risk Difference = Attack rate #1 minus Attack rate #2 = 74-56 = 18

Here we selected bread from an attack rate table to show you. 74 percent of people eating the bread became ill compared to 56 percent of the people becoming ill that did not the bread. So the risk difference is 74 minus 56 or 18 percent. Usually the risk difference is large for the contaminated food and small for other foods, so, often the largest risk difference identifies the contaminated food.

If the source of the outbreak has not been determined, meal-specific, or facility-specific attack rate tables can be used to focus on possible sources. The attack rate table can be used to test the strength of the association between the suspected food and the illness. Measures of association will be discussed in the drama and in future lecture modules.

Control Measures

Throughout the investigation, control measures should be implemented as appropriate to prevent additional cases. Corrective action may be needed immediately such as embargoing strongly suspected foods, and excluding or restricting ill workers. Even if the agent is not known, personal hygienic practices and critical food handling procedures can be evaluated and corrected as needed. The source could be the foodservice personnel, equipment, preparation procedures, a processor, grower, harvester, flock, farm, growing waters, and so on. Before initiating any control measures, contemplate the effectiveness, timeliness, public acceptance, costs, available resources, personnel requirements, and ramifications of any actions taken.

If humans are potential reservoirs for the suspected agent, and employees are suspected as a source, the appropriate public health response should be planned

with the help of a medical epidemiologist Once the agent is confirmed, specific control measures for the agent can be administered. For example, administering IG to those exposed to hepatitis-A within the last two weeks can help prevent additional cases. Also, after the control measures have been implemented, a mechanism must be provided to assess the effectiveness of control measures and adjust them as required.

An individual exposed to the original source would be referred to as a primary contact and a primary contact who becomes ill can be referred to as a primary case. If the pathogen is transmissible person-to-person, like Shigella, and another individual is exposed to a primary case through a plausible means of transmission, then this second individual can be referred to as a secondary contact. If the secondary contact becomes ill, then they can be referred to as a secondary case. Onset for secondary cases is usually one or more incubation periods after initial exposure of primary cases. If a contact is not ill during the interview, then that persons' risk of infection must be assessed based on the individual's susceptibility or immunity to the agent. If a case is susceptible but not ill, consider obtaining specimens to determine whether the person is infected. This would be particularly good where an asymptotic case may occur or where there is a long incubation period.

News Media Communication

As we all know, the media can become involved in the investigation. Sometimes it is the press contacting the department for information about an outbreak. Other times it is the department notifying the media to get a message out to the public to aid in an investigation or warn the public of a problem. Either way you want the public to be involved, reasonable, and solution-oriented. You will earn or lose public trust by the way you handle communication. In the example we've been discussing, several hundred customers may have been exposed to the *Hepatitis-A* virus at the Sandwich Shop. Transmission of the virus can be controlled if the customers who ate at the shop between March 15th and March 31st were informed about the possible exposure and offered immunoglobulin. (Editor's note: Often, control of the situation is not this straight forward.) Alerting the public may prevent further spread of the virus.

It depends on the situation. As a government employee, remember that you work for the public. Accept the public as a legitimate partner. You set the pace to resolve the problem and guarantee accurate information, if you're the source. Inform the public as soon as you can. A delayed information release may result in distortions of the facts or even attacks by the press. People often respond to stress and uncertainty with anger or they may overestimate the risk. So your credibility and competence will be judged by the way you communicate to the public.

Avoid complex scientific arguments and don't try to deny an outbreak's importance. You can't just present numbers, either. It's your job to put those numbers into perspective, with comparisons that people can understand. Risk is seen in different ways, depending on whether someone can control the source of

the trouble, how much they understand the risk, and the consequences that might result.

Be accessible to the press, and meet the needs of the news media if you can. Listen to the public's concerns. Don't make assumptions about what people think. Any perceived problem has to be resolved, whether a risk really exists or not. Evaluate the information you have, and then try to put yourself in the place of your audience. Educate your reporters, and tailor your communication to the specific groups and media involved. Be clear about the risks. Evaluate the information you have and be honest if your data is uncertain. Any illness, injury, or death is a tragedy, and this should be reflected in your communications to the public.

As soon as you begin investigating an outbreak, notify your public affairs office. Find out who the best person is to answer questions. A spokesperson is a leader who gets out the information, not just someone who answers questions. The public really wants to know: "Is it safe?" Get the details ready and plan for what people will ask. When you speak to the news media, you're already communicating with the public. So, avoid complex language and jargon. Instead, use concrete images that make the data come alive. Communicate on a personal level with your audience and use comparisons that put risk in perspective. Avoid non-food comparisons because comparing foodborne illness with the risk of physical trauma or other unrelated hazards does not provide useful information. Above all, keep it simple! Whenever possible, it may be best to provide a carefully prepared press release with the tangible and accurate facts to avoid speculation and careless interview statements.

The media is looking for short "sound bites", so avoid long explanations that may be taken out of context. Keep your interview to 30 minutes or less. Be careful what you say around microphones and tape recorders. There is no such thing as "off the record". Any conversation or stray comment is fair game for the media.

You can use a three-prong approach: explain the subject, state the facts, and give the context. "Boil down" the subject, the facts, and the context to 30 seconds or less. That way, the media will get their "sound bite" and you'll get the satisfaction of knowing your message is clear.

Sometimes reporters are more interested in politics than risk. They are looking for a story angle: controversy, emotions, and visuals for television or print news. When public health and the media have very different agendas, the communication gets complicated. Don't be naïve. Give the media your spin, but be careful not to become the story. An unexpected question may catch you off-guard. So think before you answer a question, and if you don't know the answer or aren't sure, say so. If it's not in your field of expertise or the information just isn't available, admit it. Only promise something if you can do it.

Listen to each question, and really focus on what is being asked. If you're not ready to respond to questions, say so, but also say when you will have some answers. Then take the time to really think through those answers in advance.

If you don't understand a question, ask the reporter to rephrase it. Never try to bluff an answer, even if a reporter expects you to know everything. Don't answer "No comment" if you can. This looks to the viewer like you're saying: "I am hiding what I know." Even after the interview is over, if you're not sure you got the facts right, contact the reporter again to clarify.

Make sure you work with all local, state and federal agencies who are investigating the same foodborne outbreak. It is critical to coordinate the release of information to the media. At the outset of a foodborne illness outbreak that goes across state lines, all agencies should get together and discuss a strategy for informing the public immediately.

This is the only way to avoid inaccurate, confusing, or conflicting messages. The agency that issues the press release is considered the lead for media contacts. If more than one agency issues information, determine the main message and keep it consistent.

If more than one agency will be speaking to reporters, you'll need phone numbers, fax numbers, and beeper numbers for each contact including after-hours numbers.

Decide up front what information is going to be included in the press release and what to tell consumers.

Before you issue a press release, share a draft with any other agencies involved, so that all errors can be corrected. After it's issued, keep in contact with each agency to discuss media follow-up.

Environmental Investigation and Food Hazard Review

Objectives

On completion of this module, participants will be able to:

- Discuss the process of the food preparation review and identify contributing factors leading to foodborne illness.

Food Prep Review

At this point in the investigation, you're well under way, having gone over surveillance data, determined number of cases, assembled your cross-disciplinary team, and met to discuss possibilities and theories. Now the focus shifts to the food hazard review. This is the "grunt work", the sometimes down and dirty stuff, but it is the key activity for health and food regulatory personnel in outbreak investigations. Within the investigational community, this step has been informally named the food prep review, and you'll see why in just a moment. In any event, it is the environmental leg of our three-legged stool and focuses on the food, methods of preparation, and possible contributing factors at the suspect food-service facility or plant.

An investigation driven by the possibility of a foodborne illness outbreak is not a routine inspection to identify regulatory violations. The food prep review is done on each suspect food or menu item that has been consumed. It concentrates on possible foods for source, means, or mode of possible contamination. You consider the ways a microbial contaminate could survive or grow. You identify actual and potential hazards associated with each ingredient, the processes used, and the way the product was transported as compared to its final use.

Let's be clear about the nature of any food preparation: there are potential hazards associated with each ingredient, the operations used, as well as storage and handling. The hazard analysis of an "epi" investigation considers those potential hazards including: the source of ingredients, the recipes, the processing equipment, food storage, preparations from the back door through the front door and beyond if necessary, time in processes and storage, and expertise and attitudes of the people involved. You're trying to recreate what happened in the past that may have resulted in foodborne illness. You focus on determining what DID happen; not what we think happened. Thus, all foods suspected during an investigation are subject to a hazard analysis.

The food prep review should identify the vehicle that caused the outbreak. In a perfect world, it would be done without knowledge of what food was implicated by the "epi" thought process. It would independently come to the same conclusion. When performing the food prep review, the investigator will go in with some prior information and initial hypotheses. It always helps to have a point of departure; a base of knowledge or ideas. Think of it as having a bag filled with possible hypotheses, and then as you go through the investigation you eliminate unsubstantiated ideas and theories based on what you can prove. If you've done it right, whatever's left in the bag at the end of the investigation is more than likely the vehicle and contributing factors. This may seem as if you're traveling the Catskills with an atlas of the world! But you must consider all possible factors, instead of being tempted to pre-judge the results.

Unfortunately, some hazard analyses are preconceived investigations. What if victims have *Salmonella* enteriditis infection and the investigator sets out to prove that eggs caused it? Or if an investigator hears *E. coli* 0157:H7, then does an investigation to prove that hamburger caused it. That's just not good science! We find it best to avoid a biased approach.

A food prep review is quite distinct from other kinds of activities that concern environmental health, in that it looks back. You're trying to identify actual and probable hazards from what happened hours or days or weeks before to the final use of each food substance. After interviewing people, making observations, and collecting samples, you come to the best possible conclusion as to how the vehicle was produced, transported, prepared and served. Then you report the findings and conclusions as to what food was the vehicle and what were the contributing factors. Sometimes there's a tendency to report speculation as findings and conclusions. You'll want to avoid that and strive to report what you actually found. That doesn't necessarily mean you completely disregard your "gut" feelings. There's a place for those personal observations and we'll talk about the comments portion of your final report a bit later.

HACCP

One type of inspection that could be confused with the food prep review is the Hazard Analysis Critical Control Point system or HACCP. In HACCP, you're trying to prevent problems from happening in the future. So the process includes a review of the procedures going on today, in order to develop a system that will prevent people from becoming ill. A normal HACCP review does not usually result from an outbreak investigation. But if the hazard analysis during an epi investigation reveals significant food safety breakdowns, one of the recommended control measures may be a HACCP system for the facility in the future. Because HACCP is a preventive program, it's really quite different from a food prep review, which is after the fact.

When an investigation implicates a food and suggests that contamination may have occurred sometime prior to its preparation in the facility, it's likely that a trace back investigation would occur. But first, it's very important that you've been able to establish that other likely causes of this kind of illness did not occur at the point

of service. Using our previous example of *Salmonella* enteriditis, shell eggs have been identified as a source of that infection. But food workers and improperly raised poultry could also be the culprit. If during the investigation you systematically and scientifically eliminate other possibilities, leaving only the eggs, then a trace back investigation is warranted to identify the source flock.

What do you do with the information collected in an outbreak hazard analysis?

Many regulators view the food preparation review in the legal context, in light of violations. Although it's true that we can find violations, the hazard analysis findings and conclusions have other significant meanings. By identifying the contributing factors, we make sure that the establishment does not repeat these problems in the future. Information from many investigations can be summarized to look for trends or most common contributing factors over time. Determine your priorities for food safety programs and the education programs provided. The information collected from one investigation can have significance that goes far beyond that investigation when pooled with the findings from previous investigations.

Contributing factors include contamination, the survival of pathogens, the persistence of toxins, and multiplication of pathogens. For bacterial hazards, two or more of these factors usually occur sequentially before an outbreak occurs. Here's a list of contributory factors derived from foodborne illness outbreak data from several countries.

Significant factors that contribute to contamination of foods are:

- Raw foods that are initially contaminated
- Infected persons who touch foods that are not heat processed for a kill step.
- Cross-contamination from raw foods of animal origin via workers' hands, cleaning cloths or equipment to food that is not heat-treated.
- Improper cleaning and/or sanitizing of equipment
- Obtaining foods from unsafe sources
- Contaminated foods or ingredients eaten raw
- Heavy metal containers or pipelines used to store high-acid foods with subsequent leaching of the toxic substance into the food.
- Seam defects or breaks in cans or packages of food leading to penetration by microbial contaminants.
- Adding substances in quantities that would create a food-safety hazard.

- Poisonous substances that contaminate foods by accident, from carelessness, improper storage, or mistaking these substances for food ingredients.
- Contamination during storage.
- Untreated sewage, sludge or manure used to fertilize produce.

Factors Affecting Growth

The length of the lag phase and the slope of the log phase are affected by the following environmental factors.

- Nutrients
- Availability of oxygen
- Temperature
- pH
- Water activity (a_w)
- Presence of inhibitory substances
- Microbial interactions
- Previous stress
- Time

Significant factors that affect survival of microorganisms or persistence of toxins are:

- Inadequate time or temperature or both during cooking, heat processing, or retorting
- Inadequate time or temperature or both during reheating of previously cooked foods
- Inadequate acidification or slow and inadequate fermentation or starter culture failure.

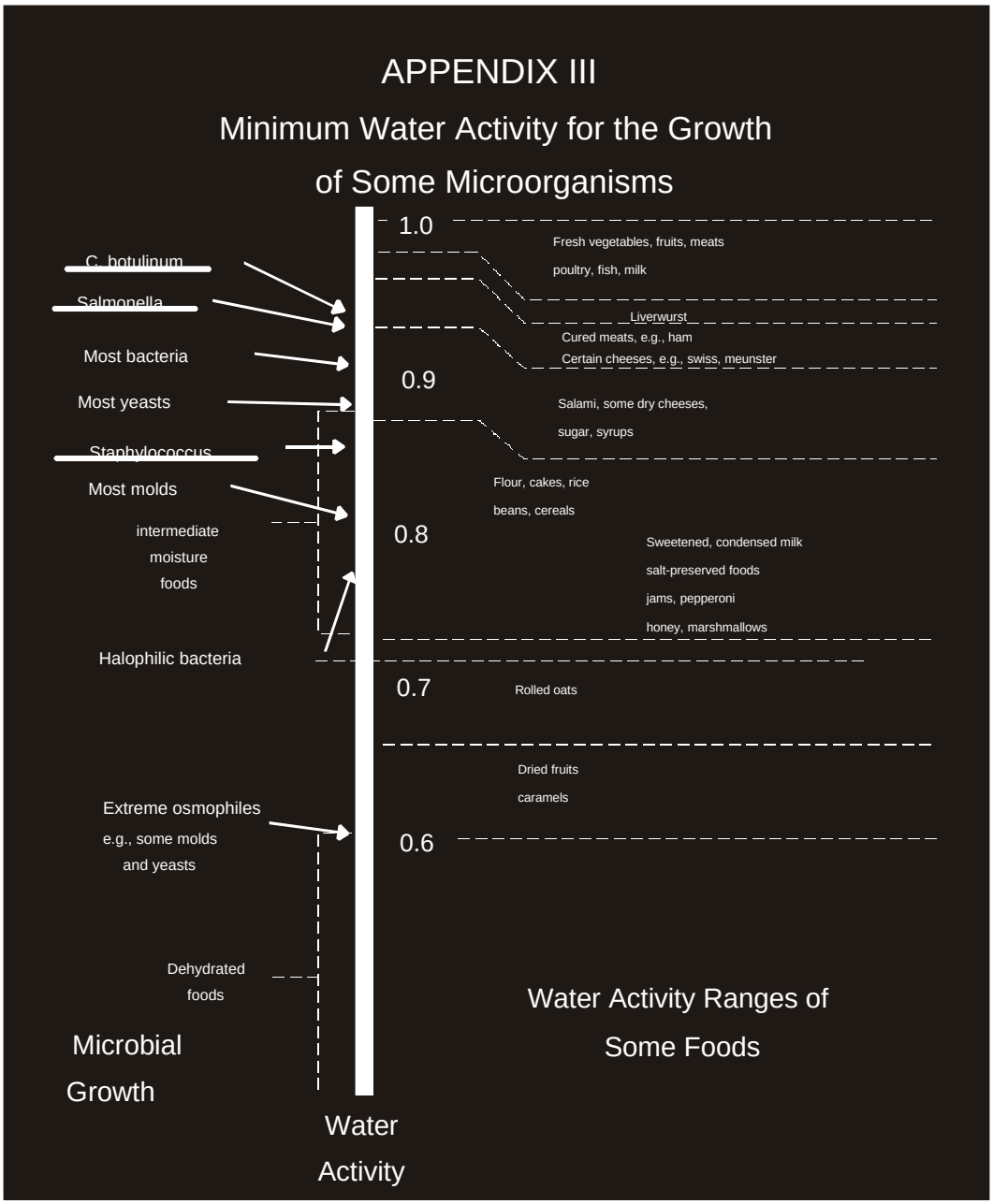
Significant factors that affect microbial growth are:

- Storing foods for a few hours at a warm room or outside temperature.
- Improper cooling of foods.
- Improper hot and cold holding temperatures.

- Holding foods for 12 hours or longer from preparation to consumption.
- Storing foods for a few weeks in refrigerators
- Inadequate preservation by insufficient concentrations of curing salts or exposure to curing salts for too short a time
- Elevated water activity of low- and intermediate-moisture foods
- Inadequate acidification of foods needing a pH of less than 4.6

Water activity is a measure of free moisture in food. Water activity is defined as the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Additional information on water activity:



Source: FDA/CFSAN, Foodborne Pathogenic Microorganisms and Natural Toxins

Potentially hazardous food does not include (other conditions also apply):

- a food with a water activity of 0.85 or less
- a food with a pH level of 4.6 or below when measured at 24 degrees C. (75 degrees F.)

Planning the Food Prep Review

The first step in planning the investigation may take place in the office before you leave for the site. Consider and identify where to find the records you need for the

investigation. The type and availability of records will vary with type of facility. For example, a retail food establishment and a food processor would have different records available. If these records do not exist in your files, they may still be available from the firm.

Review your files for:

- Menus, recipes, or product formulations. These may be commercial confidential records and must be treated accordingly.
- Processing records
- HACCP records, monitoring records, or time-temperature logs. Flow diagrams
- Complaint records
- Cleaning records
- Product challenge testing or product laboratory results
- Past inspection records to gain an impression of the menu and overall operation of establishment.

If these files exist at the establishment, then ask for them on-site. Remember, in some jurisdictions if information is commercial confidential, then the firm would be within their rights to refuse to supply it to you. You will also want to bring the materials you assembled so carefully prior to the outbreak. The equipment for measuring temperatures, pH and water activity is essential. Make sure the sampling kit with your forms comes with you. Invite anyone who has regulatory responsibility to come with you on the investigation. They'll find the investigation instructive as well. The last inspection could have been months or years ago. Also, procedures may have changed since the last inspection visit.

When you conduct an investigation, you usually have a hypothesis in mind at the outset. You're thinking that it could be bacterial, viral, toxin, or a parasite. Maybe you already know the pathogen. If that's the case, review the facts about the organism. Ask yourself, what type of environment is it likely to be in? What kind of environment does it survive in? Where could the food have been contaminated? What kind of an environment can it grow in? And then, of course where are the opportunities for growth in the food prep? If it's 0157, you're assuming that it was in a product that wasn't cooked, or maybe contaminated after cooking, or not cooked enough.

Thinking in terms of the epi Triad – agent, host and environment - where can you find the organism? Are humans a possible host for the organism? Are there other environmental sources? Any other ways this could have come into this establishment? How about the type of water supply this establishment has? Some of these outbreaks go back to a water supply as the source. If a plant has processing records, you can check their documentation. If they have a HACCP system in place, the documentation should tell you when the process went out of

control and how they responded. Review the monitoring records for the date, time and temperatures recorded, as well as the names of those who were responsible. Note any entries which deviate from critical limits, and the corrective actions taken when deviations were noted. You can get valuable insight from these records.

Food processors also keep records of consumer complaints. These records may give you insight into other problems with a product that you're investigating. Processors and plants have records of all their suppliers. Large food processors have very detailed information. They'll have a microbiological analysis on every lot of ingredients that comes into the plant, including the name, date and time it was received. Restaurants vary in their record keeping. Shellfish containers, for example, are required to have a tag on them. If an egg carton is still there, you've got a lot of information on the side of a container. Look for those kinds of records as well. Copy bills of sale and receipts. You might also be looking at credit card slips, to find other people who were at risk. Find all the records you can for the time period in question. Recipes should be on the premises. You can begin your flow diagram from either their recipe or information from your initial contact with the manager and staff.

Preparing to interview the manager is a little different than preparing to interview cases and controls. Review the information you have about the facility before leaving the office, and think through your objectives before you arrive. As soon as you get there, identify yourself to the manager. Explain who you are, your purpose for being there, and ask for their cooperation. As you begin your series of interviews, start first with the manager and discuss the circumstances that were involved in the situation you're investigating. Next, interview any employees who may have had a role to play in the processing or preparation of the food. Be sure you interview each one individually and in confidence. They might be intimidated by others or distracted by what's going on around them. Also, be careful not to close your mind to information that would lead you away from your hypothesis.

What happens if a manager doesn't want to cooperate?

Tell the manager your investigation begins with an open mind. If the place did cause the illness, they will want to take whatever steps they can to prevent problems from occurring in the future. No one wants to think that they may have caused illness. How about a positive approach? Explain that you might show the place didn't cause the illness at all. But at the moment, there's an allegation that this place made people sick, so it's your responsibility to collect the information.

Once you get the manager's cooperation, what's next? Sit down with him or her and go through each sequential step of processing and preparation for each food being investigated. This history will include: ingredients, procedures at each stage of processing, the equipment used, all potential sources of contamination during preparation, and the time and temperature conditions to which the foods are exposed. Get the recipes or product formulations. List names of everyone responsible for each significant operation. Begin sketching your flow diagrams based on the information in this interview. The manager should first tell you the

information in an interview setting, then follow up with a walk-through of the processes.

It's time for several interrelated steps that often happen at the same time. You'll be observing the actual or reconstructed operations, interviewing any employees responsible for each step, looking into employee health and hygienic practices, drawing the flow process and recording your observations on the diagram. Observe each operation from start to finish. Next, ask to interview all the workers who would have been involved in that situation, at that date and time. Interview them confidentially and be sure to use open-ended questions that let them tell you the answers. Ask them what role they played, the steps they performed, and find out if they recorded any measurements such as temperature. Make sure you record that information on the flow diagram. Observe their procedures as they work. Initially, they will feel uneasy being observed but as they concentrate on their work, you'll be able to verify what they told you.

Your purpose for gathering all this information is to look for any contributing factors in the process such as: Could contamination have been introduced by workers' hands or their hygienic practices? Is the equipment dirty? Any chance of cross-contamination from other foods? Are the heating or cooling processes being measured? The job's not over when you observe the first flaw that supports your hunch. Other practices also could have been important contributors to the outbreak. At every step of the process, you are evaluating each employee's answer by considering three aspects: contamination, growth or proliferation, and survival. How likely is it that incoming foods brought foodborne pathogens into the establishment? Could contamination have been introduced here? Would it have increased in numbers here? And if so, to what degree? Or could it have simply survived here? If so, was there an error that would have allowed that pathogen to survive?

Maybe organisms would have been destroyed if things were done properly but something went wrong. Find out if anyone remembers what happened on a given day. Help them remember, back in the context of the time and place where it happened. Ask questions like, "What were you doing that day? Was anything unusual? Was something not working that day? Any particular problems? Were deliveries coming in on time? Was all equipment working properly? Was someone out ill? Were you short-staffed? Ask if they were preparing large quantities of food for the next day. Was the advance preparation because they didn't have enough hot or cold facilities for the day of the event? But remember, don't ask with a leading question. It would be better to ask: "Why were large amounts of food prepared in advance?"

Interview each worker and determine if any were ill. Find out if they had any significant symptoms. You might have them tested for the organism of concern. In some health departments, stool cultures are automatically collected on all kitchen employees to assure that no one was shedding any pathogens at the time of the examination. Of course, if an employee is found positive for the agent of concern, then you have more research to do. Is this employee a victim because they ate the same food or were they the source of the problem? It's very important that

you get enough information to differentiate between the two. Find out who worked on certain days and determine if any were ill. Review the record of attendance and the jobs people were doing.

Now, let's look at collecting specimens and samples. You're at the site, interviewing people, setting up the flow diagram, and starting to walk through the procedure. What environmental and food samples are necessary to collect at that point? There are a number of things to consider. Some people take all kinds of samples, and some may not be necessary. It can be worthwhile to take environmental samples like swabs of work surfaces or equipment utensils like slicers and knives. Usually, you've arrived at the site quite a while after the fact. So, it wouldn't be a total surprise if you couldn't collect the agent in environmental or food samples. But what if the facility isn't doing a good job of cleaning? Maybe when you examine the equipment you find it hadn't been cleaned in a long time. If so, there's a good chance you're going to find the agent. The general level of sanitation will often point the way to the answers you're going to find.

It's often difficult to get food samples because there's no original food left. If there is food left from the implicated time period, definitely collect it. That's the most valuable sample you can get. Even if that leftover food has been in the garbage can, take it aseptically, anyway. For certain agents, the sample from a garbage can is still just as valid as a sample from the container in which the food was stored. Even if the result of a sample has no legal status, it can still inform the investigation. You may also have to collect specimens from workers, either stool specimens or swabs of the nose or wounds as in the case of *Staphylococcus* aureus.

If you have ingredients and you know those ingredients led to the make up of the implicated food, definitely take a sample for testing. Some agents can survive in these ingredients for quite a while. If it's a chemical agent or toxin then you're not worried about survival anyway. How far back can you go to collect ingredients? That is, if they don't have the implicated food, how far back can you go to get samples? If they have any of the ingredients there, test those, up to a point. Do not necessarily test spices like pepper and salt unless there is evidence they were the problem.

How far forward can you go to get food that has been prepared since the time period of concern?

Let's say you suspect a particular dish as being the vehicle, but that dish is all gone. However, they've prepared it on several occasions since then. In fact there's some there today. Collect that food. We call those check samples. It has very little scientific significance because a negative sample tells you nothing. You're not testing the food the people ate. In this case, a positive sample is going to create some confusion too. You've just got to be very careful how you interpret the finding because there's no connection yet. You'd need to make that connection through your interview. Ask them if they used the same utensils. Ask about their procedures for cleanup, and how often it's done. It's got to be a much less directed question.

You want to know what happened at some point in the past, not what's happening today. You've got to be very careful that what you're measuring or sampling today has some relevance to what happened when the implicated food was prepared. You can over- or under- interpret the information. There's one exception! If you've got an ongoing outbreak situation, then an implicated food sample can be very relevant. For example, several years ago a rare serotype of *Salmonella* was identified in two small children and recovered from a food they had eaten. The product was manufactured here in the U. S. Environmental samples were collected and the same species of salmonella was recovered. The product was immediately recalled. So sometimes you can take microbiologic samples long after the fact and still find the agent, that same bug that caused everybody to be sick.

You need to weigh that finding carefully. It has both epidemiologic and regulatory significance. Deal with it in the two different arenas. There's no guarantee that even if you do a thorough environmental sample, you're going to find the agent. You may and it can provide a lot of insight if you do. I have seen results of samples collected long after the fact that weren't the same food. The investigators tried to fashion these findings into a conclusion. Trace contaminated food back to the source where the contamination occurred. Investigations often involve concerns about food sources and require trace backs.

Review records on ingredients, including when they would have been received, and what documentation they have on receipts. It can even get down to the type of packaging the food comes in. Ask if they still have the shipping container. Ask for other containers from the same shipment. Maybe they used up one container but there are still other containers from the same shipment. Ask what time of day the deliveries arrive. Delivery time should implicate the supplier, depending on what lot the distributor was sending out. Determine the color, size, and code numbers. For some products, you may need to know the grade. Find out how it was packaged. That can make a difference when it comes to trace backs. Anything on the package that describes the ingredients is helpful too. If it's hamburger, note the grind. How coarse was it? How much fat was in it? 10 or 20 or even 30 percent fat? Was this blended hamburger from several sources or was it from one source?

Was the produce locally grown or did it come from somewhere else? Do everything you can to describe the ingredients in the product. Is there anything to document the source of the product or where it was shipped from? Typical information includes how it was received, packaged, and stored. All of that can be important in the trace back. Then there's "trace forward", which is a technique for expanding and finding additional cases from the epi point of view. Do we have other people still at risk? Do we need to go public with this? Let's say you've discovered a bad lot of some food item. You trace it back to the distributor and find it was delivered all over town. You can still prevent additional exposure or identify additional cases. We'll be concentrating on this aspect of the investigation in an upcoming program entitled "Trace Back Investigations".

How do you identify contamination, growth, and survival opportunities?

- Analyze each recipe
- Analyze each ingredient
- Are pathogens or chemicals present? What are they?
- How severe is the outcome and risk of occurrence?

Analyze each recipe or formulation for hazards. Analyze each ingredient, noting its potential for being a contaminant. Get the ingredients used by either reading the recipe or watching their incorporation into a product. Ask the following questions and record the information: Are pathogenic microbes, toxins or chemicals of concern likely to be present? If so, what are they? How severe is the outcome and risk of occurrence?

- Were any returned goods, reworks, or leftovers used as ingredients?
- Are preservatives or inhibitors used?
- What are they?
- Are excessive amounts used?
- Are improper amounts used?
- Was there an omission of an inhibitor?
- Was there a proper acidulent used
- Was there a proper humectant used?
- Does the final product have any abnormal characteristics?

Were any returned goods, reworks, or leftovers used as ingredients? Are preservatives or other substances that either kill microbes or inhibit their growth used as ingredients? If so what are they? Are any of the ingredients hazardous if used in excessive amounts? Are any of the ingredients used in lower than recommended amounts? Was anything left out that's needed to inhibit microbial multiplication or spore outgrowth? Do the amount and type of acidulent and the resulting *p*H of the final product affect growth or survival of the pathogen? Does the type of humectant and the water activity (aw) of the final product affect growth? Or, do they affect survival of pathogens during processing? Does the final product have any abnormal characteristics?

- Possible contamination during transport, receiving, processing, preparing or storage?
- Worker's hands?
- Equipment surfaces?

- Cross-contamination?
- Physical contaminants?
- Was there a proper kill step?
- Proper reheating?
- Proper acidification and fermentation?
- Was there contamination after processing?
- Cross-contamination from a raw product?
- Were controls manipulated?

The following two tables includes additional information on pH ranges:

MICROORGANISMS AND pH

ORGANISMS	OPTIMUM pH
Salmonella spp.	6.0 - 7.5
Staphylococcus spp.	6.0 - 7.0
Escherichia coli	6.0 - 8.0
Most Bacteria	5.5 - 8.0
Yeast (spoilage organisms)	4.0 - 6.5
Molds (spoilage organisms)	4.5 - 6.8

pH VALUES OF SOME FOODS

NOTE: VALUES WILL VARY BY SOURCE

PRODUCT	Approximate pH Range
GROUND BEEF	5.1 - 6.2
HAM	5.9 - 6.1
CHICKEN	6.2 - 6.7
FISH (most species)	6.6 - 6.8
OYSTERS	4.8 - 6.3
BUTTER	6.1 - 6.4
BUTTERMILK	4.5
CHEESE	4.9 - 5.9
MILK	6.3 - 7.0
YOGURT	3.8 - 4.2
VEGETABLES	3.1 - 6.5
YELLOW ONION	4.8
FRUITS	1.8 - 6.7
ORANGE JUICE	3.6 - 4.3
MELONS	6.3 - 6.7
MAYONNAISE	3.0 - 4.1

Evaluate the operations for potential hazards by reviewing each preparation or processing step. Ask the following questions: Could the product be contaminated during transport, receiving, processing, preparing or storage? Consider the hands of workers, equipment surfaces, cross-contamination from raw materials, leaking valves or plates, dead ends, or physical contaminants. Also, when was the last time equipment was tested and calibrated?

Would pathogens or toxic substances be inactivated during heat processing, reheating, or other processes including acidification and fermentation? Could pathogens or toxic substances contaminate the food after processing? Consider the possibilities of subsequent handling. Are there opportunities for cross-contamination from a raw product? Could someone have manipulated the controls to shorten or bypass a process designed to ensure safety?

Time and temperature sequence of operations.

How could the package or container influence the survival or growth of pathogens? Would it allow chemical contaminants to migrate into foods? Is a modified atmosphere such as vacuum packaging or oxygen exclusion being used? What pathogens would survive or multiply in this process environment? How effectively were the equipment and utensils cleaned and disinfected? What was the sanitizing solution's concentration, temperature and time of exposure? Which processing or preparation steps were especially intended to eliminate, inhibit, reduce, minimize or delay the hazard?

- Time/temperature sequence?
- Did packaging influence pathogens?
- Did chemical contaminants get into food?
- Is modified atmosphere being used?
- What pathogens would survive or multiply in this process environment?
- Was equipment and utensils cleaned properly?
- Was proper sanitizing solution used?
- Were any special steps used?

Measure and record the temperature of implicated foods at both the completion of the initial heat processing or reheating; and include post-cooking chilling. Use your dial or digital thermometers, thermocouples or potentiometers. You may also want to check in-line or recording thermometers as well. Measure cook times with a stop watch, timer, or from potentiometers or recording devices. Record the time and temperature data on the flow diagram and your records. For foods cooked in retorts or pressure cookers, evaluate the operation of the equipment. Check the temperature and time of processing, venting procedure, and adequacy of sealing, rather than the temperature of the product.

Examples of thermometers:

- digital thermometers
- thermocouples
- potentiometer
- in-line or recording thermometers

Also check to see if temperatures and holding times of foods are within a range where bacteria can multiply. If so, is the rate likely to be rapid or slow? Evaluate how fast foods cool in refrigerators and in other cooling devices.

Measure the dimensions of containers used to hold foods being cooled. What is the depth of the food mass? Record these figures on the flow diagram. From your measurements, estimate probable cooling rates and the potential for microbial growth. Check to see how foods are covered. Something like “foil over plastic” is great to prevent further contamination and odor transfer, but it may impede cooling at the same time. Are containers stacked on top or against each other? Where the containers are located in refrigerators may affect cooling or result in cross-contamination. The type of cooler is also important. Is it forced-air flow or some other type of rapid cooling?

In some investigations, you may have to verify the pH, water activity and other parameters such as acidity so be prepared. Field instruments are available to measure the pH, and in some cases water activity. If these are important issues, ask the lab to do the analysis for more precise results.

From the initial interview with the manager, you’ve started a flow chart of each food item for lots of reasons. It keeps you in the ballpark and it’s good feedback in case you and the manager are not talking the same jargon. But as you interview different people, you’ll be modifying that diagram as new information comes in. This will then change some of the facts you have as well. The flow diagram helps to ask the right questions and to fill in the little details. For example, how big was the container at this step? How long did it cook at that step? How long would it have cooled at this step? Who did the job at this step?

Sometimes you’ll get conflicting information. One employee says the procedure was done this way and the other says no, it was done that way. Try your best to resolve the differences. For a variety of reasons, they may respond with the appropriate rather than with the actual procedure. If you can find the person who actually prepared that food, and you can put them back in that time and place, they’ll more than likely give you good information. Even if it’s not resolvable, you’ll have a notation somewhere on your flow diagram.

Data Review

One way to interpret food prep data is to plot out a time- temperature curve. Time-temperature curves allow you to evaluate if sufficient time and temperature

occurred in a food to permit the growth of microbial pathogens, specifically bacteria. It's not relevant for viruses or parasites. To plot a time-temperature curve, you need to account for the time when the food was in storage, when it was being prepared, when it was being cooked, when it was being cooled, reheated, and held for service. You want to know whether there was an opportunity for bacterial growth, survival, or destruction in all those steps.

Now, let's follow the preparation, cooking, cooling and service of a roast beef. You have a preliminary flow diagram from your talk with the manager. You'll be filling it out as you talk to each employee and note their specific tasks in roasting the beef. Feel free to draw your own flow diagram as we go through this example.

Here's a raw roast beef that was held in the refrigerator at 39 degrees for three days. Some of the pathogens that might be found on a piece of beef include *Salmonella*, *Clostridium* perfringens, and *E. coli* O157: H7. A piece of raw beef would be expected to have a water activity, pH and oxidation-reduction or redox potential that would be conducive to the growth of bacterial pathogens. The refrigeration temperature and competition from non-pathogenic bacteria would inhibit the growth of pathogens. Most of the microbial contamination would be expected to be on the surface of the meat. But, there could be internal contamination due to piercing of the meat by knives, forks, and those tenderizers that turn a tough piece of meat into something a little more chewable!

First the meat is seasoned and placed in the roasting pan. It's then cooked in an oven at 350 degrees for several hours until the internal temperature reaches 145 degrees for 3 minutes. Ignore the post oven heat rise when factoring cooking time and temperature. This cooking process would be expected to destroy vegetative microorganisms on the outside and inside of the roast, but any spores would survive the heating process.

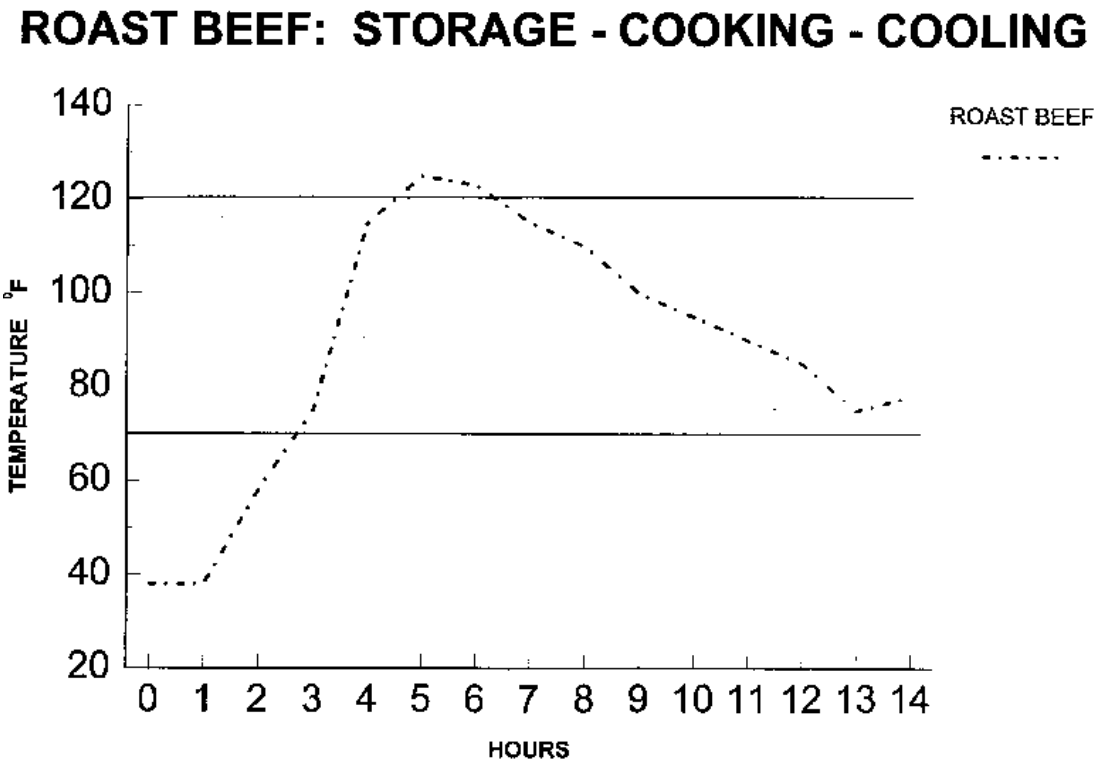
After the meat cooks, it's going in two different directions. After it is reduced in size, one part is going into the walk-in for a rapid cool-down. Tomorrow we'll reheat, slice and serve it. Now the other half can be sliced and served; we'll enjoy it when we're finished up here. Contamination from utensils or worker hands or both would survive and multiply if given the opportunity here. Re-heating to the appropriate time/temperature parameters will destroy vegetative bacteria and viruses on the surface of the meat.

Some key temperature guidelines:

- 250 ^{o} F, is a common retort temperature value that kills bacterial spores in minutes.
- 165 ^{o} F, is where vegetative forms of pathogenic bacteria are killed in several seconds.
- 130 ^{o}, is where vegetative forms of pathogenic bacteria are killed in hours.
- 122^{o} or lower is where pathogenic bacteria begin to grow.

- 70 ^{o} is about where the bacterial log phase significantly increases as the food warms up, or decreases as it cools.

The purpose of the time-temperature curve is to determine whether the food was in the growth zone or danger zone long enough to permit bacterial growth. By plotting out the number of hours of elapsed time, you can figure out how long that food was actually in that temperature zone.



Here is the actual time-temperature curve from a previous investigation. You see the lines at 120 degrees and 70 degrees. Roughly that's the range where you're going to get the most pathogen growth during cooling. By plotting out the number of hours of elapsed time, you can figure out how long that food was actually in that temperature zone. In this example, the beef was in the danger zone a relatively short period of time, as the preparation and cooking began. Then, the cooking may have destroyed vegetative organisms, on the surface. The internal temperature of less than 125 degrees for less than one hour is not what the Food Code requires. As soon as cooling begins, look at how many hours potential pathogens are in the danger zone for pathogens to grow. In this example, the center of the roast is in the optimal growth zone for at least 7 hours. If *C.* perfringens spores were present, they would have the opportunity to grow rapidly and create a potential health problem. How do you use this contributing factor information about the roast beef? Over time, after hundreds of investigations,

there are common contributing factors that lead to prevention recommendations. If cooling is a problem, you've got to have it regulated and do it properly.

Remember this is a food prep review. The purpose is to find out what went wrong and identify the contributing factors. So the EPI investigation gives you an association that roast beef was the vehicle. The food prep review in the kitchen determines how the roast beef was prepared. Now in this example the way the roast was prepared you'd probably say "Ah, Ha! I've found contributing factors that may cause an outbreak", even if there wasn't an outbreak. You have to interpret the data in the context of the agent you're dealing with. If this was an outbreak and you thought you had a chemical agent involved, it wouldn't have any relevance other than it simply is a bad practice. But if you're investigating an outbreak for *C.* perfringens as the agent, then you have the whole scenario that would be plausible. *Salmonella* and *E. coli* 0157:H7 would be the other most likely agents. Now you have a food preparation practice that's compatible with the etiology that you're investigating.

So you've got the contributing factor that supports your hypothesis that *C.* perfringens*, E. coli 0157,* or *Salmonella* is your agent. Your food prep review is corroborating the evidence. If you were investigating the outbreak before a specific food was implicated, and you did a hazard analysis on the roast beef, you would now be alerted to a new problem. You've discovered another practice that may contribute to a potential future outbreak. It may not have directly contributed to the outbreak you are investigating. But now as you are nearing the end of the investigation, you start to look at future control and preventative measures. The practices discovered in this case are then added into your recommendations.

The information that you're gathering along with the interview is vital, and may even hit the hypothesis on the head if you've done the work properly. The take home message is you've got to do the food prep review and your interviews properly. You've got to ask the appropriate questions to get the right answers. You've got to see how they did it, and you follow these procedures.

Typically you're going back and reconstructing what happened in the past. When going into an outbreak scene and investigating the roast beef that was prepared two weeks ago, you may ask the operator to reconstruct cooking and cooling. You'll observe their prep, and take measurements while it is cooking and during cooling. You'll want to recreate what happened. Sometimes you'll repeat the whole recipe. If not, you've got to interpret from what you do collect. A regulator has to be knowledgeable enough about food technology and thermodynamics to see this in his mind and know what's happening, even though he didn't actually measure the temperature.

If you put a 25-pound steamship round that's been cooked into a walk-in cooler, there's no way this mass is going to cool rapidly enough to inhibit the growth of *C.* perfringens spores. You can identify the contributing factor through interviewing, if you don't have direct observation. Then, you put the steps of the procedure together. Identify likely contributing factors. After you diagram the flow process, you want to identify the opportunities for contamination, survival, growth, and

destruction in each of these steps you observed in the investigation. Bear in mind that you want to establish what didn't happen as much as what did happen. That way you can eliminate other possibilities and be that much more secure in the conclusions that you come to.

Investigators who do these environmental investigations usually are familiar with their agents and with the contributing factors. Even if they didn't establish the fact that something happened, they have a tendency to report that it did happen. And their rationale is: well, it had to happen, because that's what happens in other salmonella or *C.* perfringens outbreak. Investigators need to report only what they established occurred in their investigations, not what they read about in other investigations. That really skews the data in this area.

When you're at the facility doing the food prep review, you may uncover hazardous conditions right then. Those conditions may have had something to do with the outbreak. Or, there may be a new one in the making. Maybe the hazard you've uncovered had nothing to do with the outbreak. Still, it has to be dealt with right there. At that point, go to management and discuss what you uncovered that is hazardous. You've got to address it, correct it, and prevent it from occurring again at that place.

If you have a copy of the IAMFES manual , keys A through D are very useful tools for generating hypotheses about agents, vehicles and contributing factors. They're also useful as a check during and after your data collection to make sure you have considered all of the appropriate possibilities.

So far, our food preparation review discussions have focused on the place where the vehicle was prepared and/or served. Some investigations will determine that contamination did not occur on site and then a trace back is conducted. To determine the source of contamination, what do we look for in the various "upstream" steps in the farm-to-table system? The same broad concepts apply to contamination, survival and growth. In distribution and warehousing systems, we need to look for contamination from vermin or non-food products such as cleaners, sanitizers, and pesticides. Also, raw food product and other items previously on the same truck have to be considered. We need to verify that refrigerated or frozen food has been held at proper temperatures. At food processors, contamination can also originate from cross connections in food piping, splashing during cleaning, ventilation systems, etc. Ingredient time and temperature during processing can allow for survival and proliferation during storage and cooling of products.

Contamination at the grower/producer level can come from: water, workers, manure, animals on farms, animal or human waste in shellfish growing areas, and infected, colonized animals for animal foods such as beef and eggs. Raw products usually have not undergone any steps to eliminate contamination. Proliferation can occur if perishable foods are not cooled quickly and held at refrigeration temperatures.

What if your investigation and hypothesis indicates that you have a foodborne outbreak that could pose a pubic health hazard? You will need to respond immediately to control and prevent future illness.

Appropriate action for preventing the spread of disease becomes necessary. The action you take will be guided by: the suspected or known causal agent or pathogen, the severity of its consequences, the population at risk, and the methods of processing, preparation and packaging the food has undergone. How is the food distributed? How are the implicated vehicles treated before they are consumed? What is the cost of potential action relative to the risk of undesirable consequences? Communication with the public involves the will to act to protect public health.

Immediate and appropriate action is justified if the disease being investigated has put highly susceptible persons at risk such as the aged, infants and toddlers. Or if there's a high probably of extensive spread of the agent, such as any *Salmonella* outbreak. Especially consider immediate action in cases of severe manifestations such as *E. coli* O157:H7 or botulism. Collect samples of the food you believe was the vehicle. The operator may want to voluntarily denature and discard the food, otherwise you will need to embargo the food. If you identify a practice that can lead to contamination, proliferation or survival you will need to see to it that the practice is appropriately modified before any additional food is exposed to that process or step. This can mean anything from cross-contamination in storage or at a work station like a cutting board, to inadequate refrigeration, cooling or cooking, to an ill employee who is preparing ready-to-eat food.

It is appropriate to discuss case findings and conclusions with epi and regulatory experts at the state or national level before taking actions. This is especially true if you're dealing with interstate distribution or large intrastate distribution. If the food is shown to be the vehicle or likely to be the vehicle then product recall or warnings to the public at risk may be initiated. The precautionary measures you initiate may be suspended when proper corrections are made and can be continuously assured; or, if the investigation later determines that the food or facility under investigation is not involved.

Clinical and Food Samples

Objectives

Upon completion of this part, participants will be able to:

- Correctly collect and handle environmental and physical samples.
- Understand the importance of control measures.
- Discuss several different types of control measures.

Personal Precautions

As you prepare to collect samples be aware that you probably don't know all the risks. So, be safe, be prudent. Assess the environment you will be working in to determine the potential severity of the situation. Collect samples in such a way that you don't endanger yourself or others.

Avoid Contamination

Make every effort to avoid contaminating a sample by your actions during the collection process. Consider all samples contaminated and potentially infectious.

Wash Hands Before and After

Hands should be washed before and after collecting samples. Wash your hands under running water with liquid soap for a minimum of twenty seconds; dry with a paper towel and use a paper towel to turn-off the faucet.

Wear Gloves

Wear gloves during sample collection if you have cuts, chapped hands, or dermatitis.

Don't Eat or Smoke

Ensure your personal safety. Avoid eating, drinking, or smoking in areas where there's a reasonable chance of exposure. When there is a risk of occupational

exposure wear appropriate protective equipment to maintain a barrier for protection. Remember some pathogens can become airborne in an aerosol.

Wear Protective Garments and Equipment

Wear a lab-coat, face-mask, and protective eyewear when splashes are likely. In general, wear a lab-coat, hair restraint, and cleanable boots to protect yourself and ensure that samples do not get contaminated. After equipment is used, treat the equipment as contaminated.

Consult With the Lab

Prior to sample collection, call your lab and ask for specific collection, storage, and transportation instructions. Talking with them can also ensure the analysis can be planned within the lab work schedule. Be sure to give the lab sufficient information to guide in the selection of test media. Transport samples to the lab promptly because non-pathogenic microbes can overgrow pathogenic microbes. The lab can only report what has been found from microscopic and cultural examination. Although it's true that pathogen detecting can be limited by the lack of appropriate assays, it's always true that inappropriate sample collection and handling will limit what the lab can detect.

Equipment

Bring the right equipment for the job and take along lots of extras. You won't be able to just go to the corner store and pickup specialized and sterile equipment. Of course, the lab will sterilize and package equipment but it's up to you to use proper technique and in-date supplies.

Samples

Samples are collected to determine where a food may have been contaminated. Aseptic sampling techniques ensure that microbiological findings accurately reflect the conditions at the time of the sample. Improperly collected specimens don't do much good. Collect at least twice the quantity of sample that will be required for analysis. Specimens from environmental surfaces must be obtained before cleaning or antimicrobial agents have been administered to these surfaces. Record product temperatures for food samples being collected and, if possible, obtain ambient air and humidity measurements. Be certain that samples are sufficiently wet with transport medium before promptly delivering to the lab. Don't let them dry out. Maintain sample integrity from collection, shipment, through analysis. Be sure the paper work that accompanies every sample can be read and understood. Be consistent with documentation and avoid changes in wording. If there are inconsistencies with the sample and paper work, recollect the sample if possible. Show the source, date, time, and your name on each specimen container. Use leak proof, opaque, puncture resistant containers to transport samples. Label each sample as a biohazard

hazardous material. Special mailing containers are required if you are sending specimens of a hazardous nature through the mail.

More than likely you'll be coming into an establishment after the illness has occurred. In the event you can't find any of the original leftovers, then take samples from a new batch of the menu item that's prepared in a similar manner. Also consider sampling raw ingredients, if appropriate. You might also consider checking the garbage for discarded product. Collect samples at your first opportunity, while they're available. Be sure to correctly identify food samples. For example, original leftovers; new batch of the same menu item made from the exact same raw ingredients as the implicated food; or a new batch of the same menu item made the same way; or the raw ingredients from the same lots as the implicated food, and so on. Even if the samples are not analyzed immediately you'll have them for later use.

As the investigation progresses, continue to implement control measures to limit the spread of the agent. Sometimes the agent can not be verified in the product, but action can be initiated if exposures are epidemiologically implicated.

When EPI, hazard analysis and lab findings don't point to the same conclusions, then reconsider the hypothesis. How else could this situation be explained? In reformulating the hypothesis, consider new vehicles and modes of transmission. For example, data for a Salmonella outbreak originally thought to be from food served at a birthday party ends up being from someone's pet reptile. One way to find out this type of information is by revisiting the cases, controls and food prep workers.

When lab results reveal negative results for implicated foods, then sampling dilemmas are encountered. Perhaps a pathogen is not homogenous throughout the product. For example, the outer surfaces of a large roast under refrigeration will cool more rapidly than at the center, which could result in the growth of existing spores or bacteria. So sampling the outer surface would not yield a true picture of the product as a whole. Or take the reverse of this concept with cooking a raw product. The outside may be fully cooked, but the inside doesn't receive an adequate heat treatment. From another stand point, even if the food was properly reheated, heat stable toxins from staph or the emetic type of B. cereus would still be virulent, but the staph or B. cereus organisms would not be found in the food sample. So it's important to understand how the food has been worked through various preparation steps in deciding how to collect samples and interpret the results. In some instances, samples from various locations of the product may be beneficial. Finally, while laboratory confirmation is always best, many investigations have been successfully concluded with epidemiologic evidence only, without laboratory confirmation of the implicated food as the source.

When the EPI, lab and hazard analysis evidence doesn't converge, there are still some things that can be done based on the strength of the evidence you have.

Generally speaking, they are to remove the product, destroy it, or deny access to the source. If initially a food item is strongly suspected but the data analysis is incomplete, then to be prudent, place that food under detention or hold

temporarily until a final determination can be made. Also, depending on the food prep review findings, it may be appropriate to implement personal hygienic and good manufacturing practices for microorganism destruction or reduction, and to prevent cross contamination. This could include a thorough cleaning and sanitizing of the facility and equipment and discarding suspect foods.

Removal of the source may include excluding or restricting ill or asymptomatic employees. In so doing, a facility could be restaffed with well or other nonsusceptible individuals, if necessary. Other options may include recall or the destruction or denaturing of existing products. Other times, you may have to close the facility or growing waters, or exclude eggs from infected flocks.

The risk of transmission remains until the agent has been eliminated, susceptible people no longer exist, or exposure to infected people is eliminated. Controls may include treating a case to become noninfectious, treating others to reduce their susceptibility, and implementing personal hygienic practices for cases and contacts. These measures include implementation and evaluating program effectiveness. Remember that the selection and implementation of control measures must address the unique characteristics of the agent and accommodate any extenuating circumstances.

Each of the following factors should be consistent with the agent: the incubation period, time of onset, symptoms and duration in conjunction with exposure to the implicated food or foods from the attack rate table. In addition, the associations and contributing factors relative to contamination, survival or growth of the agent should be plausible for the implicated foods. If laboratory and EPI conclusions support the hypothesis, but the hazard analysis doesn't, then the hazard analysis is incomplete or you may be faced with a product source issue. But, before concluding it's a source problem, re-interview food workers and if necessary, have the operation recreate the food item from beginning to end. If it's determined that contamination occurred prior to delivery to the facility, then recovering the agent from raw foods, ingredients, or from packaged product would assist in a trace back to the product source.

Enteric, Sterile, and Parasitic Stool Collection Kits

If a decision is made to collect stool samples, then only qualified personnel should collect stool samples during the acute phase of disease before antibiotic therapy has been started. Again use appropriate protective gear such as gloves and a lab coat while working with these samples. Include any mucus or pieces of epithelium in the sample. Start collecting stool specimens immediately after being notified of an outbreak, since delaying sample collection may reduce the chance of identifying the causative agent. The optimum time to collect stool samples is during the first 48 hours of illness. If possible, you'll want samples from at least 10 ill persons, assuming that at least that number are involved in the outbreak. Sometimes it will be necessary to also collect stools from well people. The volume of samples collected, the transport medium chosen, and the storage conditions used can vary based on the suspected agent. For outbreaks thought to

be of viral origin a larger stool sample is necessary; at least the size of a urine container cup. Be sure to include instructions for collecting samples when handing out stool kits. Swabs of fresh stool can also be used to culture most bacterial pathogens. When using swabs, chill the Cary-Blair transport medium about one to two hours before use. Collect at least two swabs of fresh stools from each patient and place swabs in the refrigerated media. Maintain temperature storage logs of samples. These logs can be used in figuring out whether microbes have grown or died off between sampling and testing.

Procedure for Obtaining a Swab of a Fresh Stool Sample

Insert swab into fresh stool and ensure that visible fecal material is present on each swab. After obtaining the two swabs, insert both into the same tube of medium and push them to the bottom of the tube. Break off and discard the excess top portion of the swab sticks. Refrigerate or freeze tubes after specimens are placed in them. If specimens will be examined within 48 hours after collection, they can be refrigerated; however, if specimens must be held longer than 48 hours, freeze them as soon as possible after they are collected.

Enclose each specimen in a secure container (e.g., urine cup, Cary-Blair medium tube) to which has been affixed a waterproof label. Place this container in a waterproof bag with tissue, towels, or other blotting material to absorb any leakage. Batch specimen containers, pack with ice or frozen refrigerant packs in an insulated box, and send by overnight mail scheduled to be delivered during business hours on a weekday, if possible.

Frozen specimens stool (for bacterial testing only) should be shipped in dry ice so that they remain frozen. Use enough dry ice to keep the specimen frozen until it is received at the laboratory that will process it (i.e., enough dry ice to fill one-third to one-half of the shipping container). Do not allow glass tubes to be in direct contact with dry ice; place a layer of paper or other material between the tubes and the dry ice. To prevent excess exposure of specimens to carbon dioxide, tighten the screw caps on the Cary-Blair tubes and seal them with electrical tape, or seal the specimens in a plastic bag within the container of dry ice.

Viruses

Most enteric viruses cannot be cultivated, which means they can't be amplified to increase their likelihood of detection. Therefore, it's critical that sufficient sample is obtained for the diagnostic tests to increase the possibility of isolating the virus.

If you can, hand carry specimens to the lab, or, at the very least, mail them promptly. Some enteric organisms may rapidly decrease in number after elimination.

If appropriate for the suspect agent, specimens of vomit, water, and ice can also be submitted for testing. Collect and send these specimens only after talking with the laboratory. Once again, use appropriate zip lock or screw top containers, bags or bottles to collect and transport these samples.

Reference Material on Clinical Samples and Pathogen Characteristics

Procedure for Collecting Rectal Swabs

Caution: Unless you've received specific training in rectal swab collection, do not collect rectal swabs as it is possible to injure the patient by damaging the lining of the rectum. The same is true for using a saline enema to obtain specimens. Since nurses are probably the only ones in the audience with training in the collection of swabs and enemas the following discussion is targeted to the nurses on the outbreak team.

Most bacterial pathogens can be cultured from appropriately acquired rectal swab specimens. Collect at least two rectal swabs from each patient and place swabs in refrigerated (i.e., chilled 1-2 hours before use) Cary-Blair transport medium. When obtaining swabs from a patient, first moisten each rectal swab in the holding medium, insert the moistened swab into the rectum 1 to 1-1/2 inches, rotate the swab gently, and then return the swab to the same tube of holding medium. Try to ensure that visible fecal material is present on each swab. The handling and storage of the rectal swab is the same as for swabs of fresh stool discussed above.

Blood Samples

Only qualified personnel should collect blood samples. For patients thought to have an illness caused by viruses or bacteria it may be appropriate to submit an acute-phase specimen and a convalescent-phase specimen. Obtain the acute-serum specimen as close to the time of onset of illness as possible; at most, within a week after onset of illness. Obtain the convalescent-serum specimen 3-4weeks after the onset of illness. Antibodies to viruses usually begin to rise the first week after onset of illness, peak by the fourth week, and can fall by the sixth week.

Blood Collection

Unless you've received specific training in blood collection; do not collect blood. Only physicians, nurses, phlebotomists or specially trained health personnel may draw blood. Universal precautions need to be followed for the collection of all samples of blood and body fluids. Latex gloves should be worn for the collection process. Syringes and vacutainers must be sterile and used only once. The tourniquet must be used carefully, and properly to avoid ruining the sample and causing injury. Blood is obtained by venipuncture (the amount is determined by the type of test; 5-10 ml is usually adequate). Some tests require whole blood, some plasma, and some serum. Some tests cannot be done on hemolized blood. Serum or plasma for analysis should be separated from the cells within one hour after collection of the specimen. Refrigeration will slow down microbiological processes but will not stop them. Blood samples should be refrigerated.

Submit two serum specimens, an acute-phase specimen and a convalescent-phase specimen, for each patient thought to have illness caused by viruses or bacteria. Obtain the acute-phase serum specimen as close to the time of onset of illness as possible (at most, within a week after onset of illness) and the convalescent-phase serum specimen 3-4weeks after the onset of illness. If a viral agent is suspected, for optimal test results, specimens should be collected within 6 weeks after onset of illness.

If possible, obtain paired serum specimens from the same 10 patients from whom stool samples were obtained. Ten paired serum specimens obtained from well persons can serve as control specimens in certain studies.

Collect blood specimens from adults (15 ml) and from children (3 ml) in tubes that do not contain anticoagulants (usually red-top tubes). Centrifuge the blood and send only the serum for analysis. If no centrifuge is available, store the blood specimens in a refrigerator until a clot has formed; then remove the serum and pipette it into an empty sterile tube (using a Pasteur pipette). Refrigerate the tubes of spun serum until they are shipped. Refrigerate, but do not freeze, tubes containing unspun serum.

Ship serum specimens either refrigerated or frozen. If the clotting technique described above is used to obtain the serum, ship the specimens refrigerated so that they can be centrifuged before they are frozen. Specimens can be refrigerated by placing them in an insulated box with ice or frozen refrigerant packs. Frozen specimens can be kept frozen by shipping them on dry ice. Batch the specimens and send by overnight mail, scheduled to arrive at the laboratory during business hours on a weekday, if possible.

Antibodies to viruses usually begin to rise the first week after onset of illness, peak by the fourth week, and can fall by the sixth week. Acute-phase serum specimens should be collected in the first week of illness, and convalescent-phase serum specimens from the third to the fourth week after onset of illness but not later than the sixth week.

General instruction for collection of stool specimens +

Instructions for collecting specimens	Type of agent to be tested for: Virus	Bacterium	Parasite
When to collect	Within 48-72 hours after onset of illness	During period of active diarrhea (preferably as soon after onset of illness as possible).	Any time after onset of illness (preferably as soon after onset of illness as possible).
How much to collect	As much stool sample from each of 10 ill persons as possible (at least 10cc each person); samples from 10 controls may also be submitted.	Two rectal swabs or swabs of fresh stool from each of 10 ill persons; samples from 10 controls may also be submitted.	A fresh stool sample from each of 10 ill persons; samples from 10 controls may also be submitted.
Method of collection	Place fresh stool specimens (liquid preferable) unmixed with urine, in clean, dry containers, (e.g., urine specimen cups).	For rectal swabs, moisten each of two swabs in Cary-Blair medium first, then insert sequentially 1-1.5 inches in rectum and gently rotate. Place both swabs in the same Cary-Blair medium tube. Break off top portions of swab sticks and discard.	Collect a bulk stool specimen, unmixed with urine, in a clean container. Place a portion of each stool sample into 10% formalin and polyvinyl alcohol preservatives at a ratio of 1 part stool to 3 parts preservative. Mix well.
Storage of specimen after collection	Immediately refrigerate at 4 C. DO NOT FREEZE if electron microscopy is anticipated.	Immediately refrigerate at 4 ^{o} C if testing is to be done within 48 hours after collection; otherwise freeze samples at -70 ^{o} C.	Store at room temperature, or refrigerate at 4C. DO NOT FREEZE.
Transportation	Keep refrigerated. Place bagged and sealed specimens on ice or with frozen refrigerant packs in an insulated box. Send by overnight mail. DO NOT FREEZE.	Refrigerate as directed for viral specimens. For frozen samples: place bagged and sealed samples on dry ice. Mail in insulated box by overnight mail.	Refrigerate as directed for viral specimens. For room-temperature samples: mail in water proof containers. DO NOT FREEZE.

+Label each specimen container with a waterproof marker. Put samples in sealed, waterproof containers (e.g., plastic bags). Batch collection and send by overnight mail, scheduled to arrive at destination on a weekday during business hours.

From Centers for Disease Control. Recommendations for collection of laboratory specimens associated with outbreaks of gastroenteritis. MMWR 1990;39(No. RR-14);(inclusive pages 3,6,7,9)

Instructing patients to catch stool specimens in plastic kitchen wrap draped across the back half of the toilet under the toilet seat may facilitate collection of stool specimens. One can cut open a plastic bag; tape to the toilet seat; collect the sample; then remove bag and twist closed. Or collect stool specimens in zip-lock plastic bags. When collecting a stool sample, do not contaminate the specimen with urine; urine has a harmful effect on some microorganisms.

Information relevant to outbreaks of viral gastroenteritis

		Selected symptoms*				
Causative agent	**Patient age groupings**	**Vomiting**	**Fever**	**Incubation Period**	**Duration of illness**	**Mode of transmission**
Astrovirus	Young children And elderly people	Occasional	Occasional	1-4 days	2-3 days; occasionally 1-14 days	Food, water, fecal-oral
Calicivirus	Infants, young children, and adults	Common for infants; variable for adults	Occasional	1-3 days	1-3 days	Food, water, nosocomial, fecal-oral
Enteric adenovirus	Young children	Common	Common	7-8 days	8-12 days	Nosocomial, fecal-oral
Norwalk virus	Older children and adults	Common	Rare or mild	18-48 hours	12-48 hours	Food, water, PTP,[+] ?air, nosocomial, fecal-oral
Rotavirus, group A	Infants and toddlers	Common	Common	1-3 days	5-7 days	Water PTP, ?food, ?air, nosocomial, fecal-oral
Rotavirs, group B	Children and adults	Variable	Rare	56 hours (average)	3-7 days	Water, PTP, fecal-oral
Rotavirus, group C	Infants, children, and adults	Unknown	Unknown	24-48 hours	3-7 days	Fecal-oral

*Diarrhea is common and is usually loose, watery, and non-bloody when associated with gastroenteritis.

[+] PTP = person to person.

? = not confirmed.

From Centers for Disease Control. Recommendations for collection of laboratory specimens associated with outbreaks of gastroenteritis. MMWR 1990;39(No. RR-14);(inclusive pages 3,6,7,9)

Collection of viral samples

Most patients shed viruses in the greatest amounts during the acute phase of illness and up to 48-72 hours post-recovery. Specimens for viral studies should be collected with the strictest technique and placed in sterile containers. For viral studies, place each diarrheal stool specimen, of as large a quantity as can be obtained (preferably, at least 10 cc), in a leak-proof, clean, dry container, and refrigerate. Do not freeze specimens if electron microscopy (EM) examination is anticipated. Freezing may alter or obliterate the morphologic characteristics of some viruses; therefore, samples should be kept refrigerated and should not be frozen.

Information relevant to outbreaks of parasitic gastroenteritis

Selected Symptoms

Causative agent	Patient age groupings	Fever	Diarrhea	Abdominal	Incubation Period	Duration of illness	Mode of transmission
Balantidium coli	Unknown	Rare	Occasional mucous or blood	Mild to sever pain	Unknown	Unknown	Food, water, fecal-oral
Cryptosporidium	Children, adults with AIDS	Occasional	Profuse, watery	Occasional cramping	1-2 weeks	4 days-3 weeks	Food, water, PTP,* pets, fecal-oral
Entamoeba histolytica	All groups, adults	Variable	Occasional mucous or blood	Colicky pain	2-4 weeks	Weeks-months	Food, water, fecal-oral
Giardia lamblia	All groups, children	Rare	Loose, pale, greasy stools	Cramps, bloating, flatulence	5-25 days	1-2 weeks to months and years	Food, water, fecal-oral
Isospora belli	Adults with AIDS	Unknown	Loose stools	Unknown	9-15 days	2-3 weeks	Fecal-oral

* PTP = person-to-person

From Centers for Disease Control. Recommendations for collection of laboratory specimens associated with outbreaks of gastroenteritis. MMWR 1990;39(No. RR-14);(inclusive pages 3,6,7,9)

Parasites stool; method of collection and storage.

Mix fresh bulk-stool specimens thoroughly with each of two preservatives, 10% formalin and polyvinyl alcohol (PVA) fixative,. If there is a delay in obtaining the preservatives, refrigerate untreated stool specimens at 4 C (do not freeze) for up to 48 hours. Once preserved, the specimens can be stored and transported at room temperature or refrigerated. Do not freeze

Information relevant to outbreaks of bacterial gastroenteritis.

Selected symptoms

Causative agent	Patient age groupings	Vomiting	Fever	Diarrhea	Incubation Period	Duration of Illness	Mode of Transmission
Bacillus cereus and Staphylococcus aureus	All	Common	Rare	Usually not prominent	1-6 hours	<24 hours	Food
Campylobacter jejuni	All groups Especially<1 year old and young adults	Variable	Variable	May be dysenteric	3-5 days (1-7 days)	1-4 days, occasionally >10 days	Food, water, pets, fecal-oral
Enterotoxigenic Escherichia coli	Adults, infants, children	Occasional	Variable	Watery to profuse watery	12-72 hours	3-5 days	Food, water, PTP, *fecal-oral
Enteropathogenic Escherichia coli	Infants	Variable	Variable	Watery to profuse watery	2-6 days	1-3 weeks	Food, water, PTP, fecal-oral
Enteroinvasive Escherichia coli	Adults	Occasional	Common	May be dysenteric	2-3 days	1-2 weeks	Food, water, PTP, fecal-oral
Enterohemorrhagic Eshcerichia coli	<10 years (50%), 15 months - 73 years	Common	Rare or mild	First watery, then grossly bloody	3-5 days	7-10 days (1-12 days)	Food, PTP, fecal-oral
Salmonella	All groups, especially infants and young children	Occasional	Common	Loose, watery, occasionally bloody	8-48 hours	3-5 days	Food, water, fecal-oral
Shigella	All groups, especially 6 months-10 years	Occasional	Common	May be dysenteric	1-7 days	4-7 days	Food, water, PTP, fecal-oral
Yersinia enterocolitica	All groups, especially older children and young adults	Occasional	Common	Mucoid, occasionally bloody	2-7 days	1 day-3 weeks (average 9 days)	Food, water, PTP, pets, fecal-oral
Vibrio cholerae	All groups	Common	Variable	May be profuse and watery	9-72 hours	3-4 days	Fecal-oral, food, water

*PTP = person-to-person

From Centers for Disease Control. Recommendations for collection of laboratory specimens associated with outbreaks of gastroenteritis. MMWR 1990;39(No. RR-14);(inclusive pages 3,6,7,9)

Lag Phase: Bacteria adjusting to new environment, resting stage.

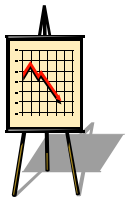
Log Phase: Bacteria undergoing ideal rapid growth.

Stationary Phase: Nutrients are becoming depleted, growth rate slows and plateaus

Death Phase: Nutrients are used up and waste products accumulate so that the overall population is decreasing.

SEE THE MICROBIOLOGY MODULE OF THE PROFESSIONAL FOOD SERVICE SANITARIAN TRAINING PROGRAM

EPI Statistics Part I



Objectives

Upon completion of this module, participants will be able to:

- Interpret statistical foodborne illness outbreak data.
- Recognize the need for different study designs.
- Be more familiar with the types of data analysis used in the investigation of foodborne illness outbreaks.

In this module we will discuss basic statistical analysis of outbreak data. Don't worry, you won't have to become a statistical expert. When we analyze outbreak data we'll need to use standard methods and be able to determine how much confidence we can reasonably place in the conclusions we reach.

The calculation of the mean, median, and range may already be familiar to some of you. These terms are included in the course manual glossary. To demonstrate measures of central tendency, we'll calculate the mean, median, and range using a small data set. These calculations are used in epidemiology to describe the population at risk. When you have a normal data distribution, the mean and median are the same. When you have extreme values, they are different. The mean or average can be inflated or depressed, depending on the magnitude of the extreme values.

The mean, or average, incubation period is calculated by adding all the incubation times and then dividing the total by 7, the number of observations in the data set.

Sample data set with incubation times for 7 cases.

Observation Case #	Incubation (hours)
1	12
2	14
3	15
4	11
5	12
6	17
7	10

Total 91

Mean = 91 / 7 = 13 hrs.

The total incubation hours is 91. 91 hours divided by 7 observations equals a mean incubation period of 13 hours.

A limitation of the mean calculation is that extreme values have a substantial impact on the results.

Sample data set with incubation times for 7 cases.

Observation Case #	Incubation (hours)
1	12
2	14
3	15
4	11
5	12
6	17
7	100

Total 181

Mean = 181 / 7 = 25.8 hrs.

For example, if the incubation time for subject-7 was erroneously recorded as 100, the mean would be 25.8 hours, not 13. When a data set contains extreme values, the median can provide a better estimate of the central or middle value.

Determining the median value and range is easier if the data is in rank order from the lowest to the highest value. The median is the middle value in a range of values that have been rank

ordered. Half the values are below the median and half are above the median. Let's walk through the calculation.

Sample data set with incubation times for 7 cases ranked in order from lowest to highest.

Case #	Rank Observation	Incubation (hours)
1	7	10
2	4	11
3	1	12
4	5	12
5	2	14
6	3	15
7	6	17

$$\text{Median observation} = \frac{\text{Number of observations} + 1}{2}$$

$$\text{Median Observation} = (N + 1) / 2 = (7 + 1) / 2$$

$$= 4$$

A simple formula for the median observation is the number of observations or cases plus one, divided by two. For our data set, it's 7 plus one, divided by two, which equals 4. So, the median observation is the fourth case who has a 12 hour incubation. Therefore the median incubation time in this example is 12. If the data set had an even number of observations, for example, if we had eight observations, then the median observation would be 8 plus one, divided by 2 or 4.5. So the median is the midpoint between observations 4 and 5. To get the median incubation time, add the values associated with observations 4 and 5 and then divide by 2. Since the median is the middle value in a rank ordered data set, the median is less sensitive than the mean to extreme values.

Sample data set consisting of 7 incubation times ranked in order from lowest to highest.)

Case #	Rank Observation	Incubation (hours)
1	7	10
2	4	11
3	1	12
4	5	12
5	2	14
6	3	15
7	6	17

Total 91

Mean = 91 / 7 = 13

Median = 12

Range = 10 to 17

The range is the interval between the minimum and the maximum values in a data set. In this example the range of incubation times is 10 to 17 hours.

Measures of Association

Measures of association were mentioned in the drama but were not fully discussed. These concepts can be difficult to grasp the first time you hear them. Don't be intimidated when we talk about statistics. Concentrate on understanding what the data is telling you. Statistics give us a standardized way to determine how much confidence to place in the conclusions we reach. Focus on what numbers mean and don't worry about the calculations. There are computer programs like Epi-Info that will do the calculations for you. We're not going to ask you to calculate any statistics on the final exam, but we will ask you to interpret data.

Let's do a data analysis little review. The epidemiologist tell us the relative risk and odds ratio are called measures of association. Use a relative risk when you have a defined population. For example, say you have a population of 100 people that attended an event and 80 of them ate the food you are interested in. If you ate the food then you were exposed. If you did not eat the food then you are unexposed.

Defined Population for Relative Risk Calculation

	People	Risk of Illness	Relative Risk
Total population	100		
Exposed, Ate Food	80	56/80 = .7	
ILL	56		
Unexposed, Did not eat food	20	3/20 = .15	
ILL	3		
			$\frac{56/80}{3/20} = 4.6$

Fifty-six of the eighty people that ate the food became ill, so the rate of illness is.7 or 70% in the exposed group. Three of the twenty people that did not eat the food were ill, so the rate of illness is.15 or 15% in the unexposed group. The relative risk compares the rate of illness in the exposed group to the rate of illness in the unexposed group. In this example,.7 divided by.15, gives a relative risk of 4.6. People that ate the food were 4.6 times more likely to become ill than people that did not eat the food were. In general, when you know the total number of people in the population you can talk about risk.

If you don't know the total number of people exposed in the population you can only talk about the “odds” that exposure occurs compared to the “odds” that exposure doesn't occur. Let me show you an example.

Undefined Population for Odds-Ratio Calculation

	People	Odds of Illness	Odds Ratio
Total population	Unknown		
Case, Ill			
Ate Food	45	45:15	
Didn't eat food	15		
Control, not ILL			
Ate food	10	10:50	
Didn't eat food	50		
			$\frac{45/15}{10/50} = \frac{3}{.2} = 15.0$

Here we do not know the total population, but we know individuals who got sick and we can select appropriate controls. Focusing on the cases, 45 ate the food and 15 didn’t eat the food.

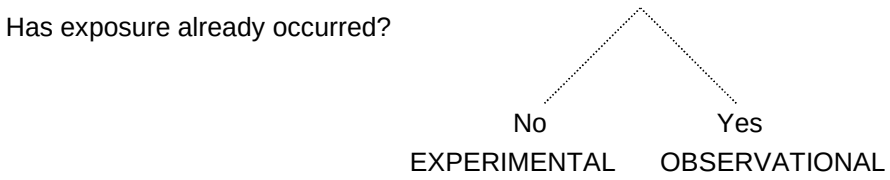
Therefore, the odds of eating the food among cases is 45 to 15. For the controls, of those who are not ill, 10 ate the food and 50 did not eat the food. So, the odds of eating the food among the controls is 10 to 50. Next, the odds of eating the food for cases is divided by the odds of eating the food for controls. 45 to 15 divided by 10 to 50, which simplifies to 15. Thus, the odds ratio in favor of exposure among the cases is 15 times greater than the odds in favor of exposure among the controls**.** Data for the relative risk and odds ratio are usually organized into a 2-by-2 table. A confidence interval is usually calculated to determine if the relative risk or odds ratio result is statistically significant. (Editors note: The 95-percent confidence interval is a range of values, which has a 95-percent chance of containing the value we are trying to estimate. In other words, if we were to do the exact study 100 times then 95 of the 100 times we would expect to get an estimate within the range of the confidence interval.)

Here is a quick review of the terms. The line-list is a spreadsheet where columns represent variables and each row represents a person. Having all the information in one place makes it easier to identify patterns in the data. An epi-curve is used to visualize the time-trend and size of the outbreak. The food specific attack-rate table is used to compare the rate of illness in those who ate a specific food with those who did not eat the food. Study design is important because the design of your study determines which measure of association will be used to analyze the data. The relative risk is used in cohort studies and the odds-ratio is used in case-control studies.

Study Designs

From a foodborne illness perspective, study design refers to the methods used to understand the relationship between exposure to a contaminated food and becoming ill. The exposure is the agent that causes the illness. The exposure could be a toxin, pathogenic microorganism, virus, chemical or some other illness-causing agent in the food. The outcome is the illness caused by the agent. When you're trying to figure out what study design to use, ask yourself, "Has the population you are studying already been exposed?"

Types of Epidemiologic Studies

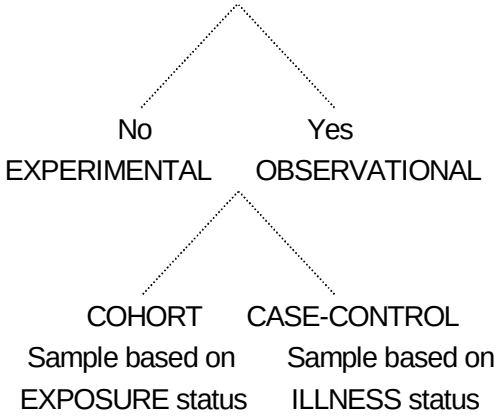


If the exposure has not occurred, then use an experimental study design. In an experimental study or clinical trial, subjects are randomly assigned to groups and all the conditions of the experiment are under the control of the investigator.

Types of Epidemiologic Studies

Types of Epidemiologic Studies

Has exposure already occurred?



If the exposure has already occurred, as in foodborne illness investigations, then use an observational study design. In observational studies the investigator analyzes the conditions of the event that have already occurred.

For investigating foodborne illness, we are basically interested in two types of observational study designs; the cohort design and the case-control design. Cohorts have defined populations.

Cohort Studies

In cohort studies we have a well-defined population, such as a banquet or wedding, and subjects are categorized based upon their exposure status to the foods at the event. People who ate a particular food are considered exposed and those who did not eat the food are unexposed. The case definition is used to decide who is considered ill and not-ill. In the Foodborne Illness Investigation drama the cohort included all persons who ate banquet food at Sandy Grove Friday evening, November 13th. The banquet guests were categorized as exposed or unexposed according to the foods they consumed. The investigator determines how many people ate a particular food and became ill, and how many did not eat the food and became ill.

Cohorts use the relative risk measure of association

The relative risk is the measure of association used in cohort studies to compare the rate of illness in the exposed group to the rate of illness in the unexposed group.

Let me explain the term, rate. A rate is a measure of the number of illnesses in a defined population over a specific time. Rates have a numerator, a denominator, and a time period.

$$\text{Rate} = \frac{\text{Number of events in a specified period}}{\text{Average population during the period}}$$

If you know what each person ate, you could calculate the rate of illness for those who ate a specific food and the rate of illness for those not exposed to the food.

2 x 2 contingency table for cohort study design

		OUTCOME	
EXPOSURE		Ill	Not ill
	Exposed (ate)	a	b
	Not Exposed (did not eat)	c	d

There were two levels of exposure to the Caesar salad: those who ate salad, and those who did not eat the salad. There are also two levels of outcome; people who met the case definition of illness and people who did not meet the case definition and were not ill.

2-BY-2 CONTINGENCY TABLE FOR COHORT STUDY DESIGN

		OUTCOME		
EXPOSURE		Ill	Not ill	
	Exposed (ate)	a	b	a+b, Total Exposed
	Not Exposed (did not eat)	c	d	c+d, Total

Alphabetic letters will be used to refer to specific cells in the 2-by-2 table. Let's first focus on the people that were exposed.

rate illness in the exposed = (a / a+b)

The rate of illness for those exposed is the number of ill persons exposed divided by the total number exposed, or, 'a' divided by 'a plus b'.

rate of illness in the unexposed = (c / c+d)

Now let's focus on the people who were not exposed, those who did not eat the food item. The rate of illness for those unexposed is 'ill' divided by the total unexposed, or, 'c' divided by 'c plus d'.

Now let me fill in the numbers from the banquet at Sandy Grove. The relative risk is the rate of illness in the exposed group divided by the rate of illness in the unexposed group.

Relative risk (RR) = (a / a + b) / (c/ c + d)

= (24/28) / (2/11)

= 4.7

In this example the relative risk is 4.7, which means that persons who ate Caesar salad were 4.7 times more likely to become ill compared to persons who did not eat Caesar salad.

Case-Control Studies

In a cohort study we sample based upon who was exposed. In case-control studies we sample based upon illness status. The investigator identifies a group of people who meet the case definition and a reference group of persons without the illness. Those who meet the case definition are called cases and those who are selected for comparison are called controls. The investigator then determines if each case and each control has had the exposure-of-interest. The criteria used for selecting controls is very important. If you plan to do a case-control study it is recommended that you discuss control selection with an epidemiologist or statistician.

All variations of case-control studies start with ill persons and an appropriate control group of persons without the illness. Then the investigator determines the frequency of the exposure in each group.

In a matched-case-control study design controls are selected because they have the same age, gender, or some other characteristic as cases.

If controls are selected because they have the same age, gender, or some other characteristic as cases then the study is called a matched case-control study design.

In unmatched-case-control study designs controls are not matched to cases based on some characteristic.)

If controls are not matched to cases you have an unmatched case-control study design.

In a case-control study you will not know the exposure status of each subject in the population. In fact, many times in foodborne illness investigations you will not know about everyone who has become ill. All you have is an incomplete list of ill persons. If you don't know the total number of people exposed in the population, you can only talk about the odds that exposure occurs compared to the odds that exposure doesn't occur. The appropriate measure of association to use in a case-control study is the odds ratio. The odds ratio tells you the odds in favor of exposure among cases compared to the odds in favor of exposure among the controls.

In some situations an odds ratio will provide a good estimate of the relative risk. For example, if the number of people with illness is small, say, under 2-percent of the total sample size, cases are representative of all cases, and controls are representative of the general population, then the odds ratio provides a good estimate of the relative risk. Use an odds ratio when you have cases and controls and use a relative risk when you have a defined population.

2 x 2 table for case-control study

EXPOSURE	Cases	Controls
Exposed (ate)	a	b
Not Exposed (did not eat)	c	d

The 2 x 2 tables for the odds ratio and relative risk look similar but in case-control studies the columns are labeled as case and control. In cohort studies the columns are labeled as ill and not ill. The formula for the odds ratios is the odds in favor of exposure among cases divided by the odds in favor of exposure among the controls.

Odds Ratio (OR) = (a/c) / (b/d)

Using the letters in the 2 x 2 table, the formulas are: odds in favor of exposure among cases is ‘a’ divided by ‘c’ and odds favor of exposure among the controls is ‘b’ divided by ‘d’. Let's say we are conducting a case-control study. We have cases that meet our case definition and we have an appropriate control group. The food we are interested in is ice cream. Here is an example.

2 X 2 contingency table for an unmatched case-control study design.

ICE CREAM / EXPOSURE	Cases	Controls
Exposed (ate)	13 a	32 b
Not Exposed (did not eat)	17 c	23 d

Odds Ratio (OR) = (a/c) / (b/d)
= (13/17) / (32/23)
= 0.55

In this example the odds ratio is 0.55 which means that ill people were about half-as-likely to eat ice cream as well people. Foods associated with an odds ratio value significantly less than 1.0 are said to be protective against illness. Maybe the taste of ice cream didn’t go well with the taste of some other food and the other food was associated with the illness!

If the relative risk or odds ratio is significantly greater then 1.0 then exposure and outcome are positively associate.

RR, OR > 1, Positive Association

If the relative risk or odds ratio value is not significantly different from 1.0 then there is no association between exposure and outcome.

RR, OR = 1 (*approximately),* No Significant Difference

If the relative risk or odds ratio value is significantly less than 1.0, then exposure and outcome are negatively associated and exposure is referred to as being protective.

RR, OR < 1, Negative Association

We've talked about the attack rate table and relative risk. Another statistic we get from these is the risk difference.

	Ate food			Did not eat			Association Measure	
Food	Total	Ill	% Ill	Total	Ill	% Ill	RR	95% CI
Bread	23	17	73.9%	16	9	56.3%	RR = 73.9/56.3	
Butter	.		.	.		.	RR = 1.31	
Fruitsal	.(17/23)*100=		.	.(9/16)*100=		.		
Oysters	.Attack rate-1.			. Attack rate-2.				
Chicken	.....			.....				
Gbeans								
Rice								
CCpie	Attack rate-1 minus Attack rate-2							
Coffee								
Bakedham	Risk difference = 73.9 - 56.3 = 17.6							
Jello								
Csalad								
Water								
Rolls								

This is the attack rate table you saw in the Foodborne Illness Investigation drama. The table shows the relative risk and the risk difference associated with bread consumption. The risk difference is also called the percent-difference. In this example, the relative risk of 1.31 shows the increase in risk for people who were exposed to bread compared to people who were not exposed. The risk difference of 17.6 shows the magnitude of the absolute change in risk for the exposed compared to the unexposed. Usually the risk difference is large for the contaminated food and small for other foods. Often the largest risk difference identifies the contaminated food. A negative risk-difference means there is more illness among those that did not eat the food. When the risk-difference is negative the measure of association would be less than 1.0.

Let's quickly sum things up. Data analysis is a necessary part of a foodborne illness investigation. Relative risk and the odds ratio are measures of association. A relative risk is calculated in cohort studies and an odds ratio is calculated in case-control studies. The relative risk compares the rate of illness in the exposed group to the rate of illness in the unexposed group. The odds ratio tells you the odds in favor of exposure among cases compared to the odds in favor of exposure among the controls.

Summary

- Relative risk and odds ratio are measures of association.
- Relative risk is calculated in cohort studies.
- Odds ratio is calculated in case-control studies.

- Relative risk compares rate of illness in exposed group to rate of illness in unexposed group.
- Odds ratio = odds in favor of exposure among cases <> compared to the odds in favor of exposure among the controls.

"Take Home Message"

RR are ratios of $\frac{\text{EXPOSED}}{\text{UNEXPOSED}}$ OR are ratios of $\frac{\text{CASES}}{\text{CONTROLS}}$

So if RR or OR = 1, there is NO DIFFERENCE between the two groups.

- RR, OR: look for BIG numbers

  >>1 for implicated foods

  0< (RR or OR) < 1 may mean food item is "protective"

- 95% Confidence Interval: SHOULD NOT INCLUDE 1

  If 95 % CI includes 1 it means the OR or RR is not significant or that there is no difference between the groups.

- p-value <0.05 or less means the OR or RR is significant

  The lower the p-value the more confident you are with your results.

EPI Statistics Part-2

Objectives

Upon completion of this module, participants will be able to:

- Be familiar with the concepts of the null and alternative hypothesis.
- Utilize p-value with measures of association.
- State criteria for inferring a casual relationship between implicated food and illness.
- State criteria for action based on EPI data without lab confirmation.

This is our last shot at discussing statistics and talking about what the epidemiologist has to consider in the analytical process of implicating a contaminated food. Again, concentrate on the steps involved in the analytical process because you will not need to calculate any statistics on the final exam. However, you will be asked to interpret statistical results. You've heard the terms "hypothesis " and "statistical significance" a number of times already. They're not new to our vocabulary. The value of taking the time to craft a hypothesis, is that it forces us to organize our thinking about possible time, place, and person associations. The hypothesis gives direction to the investigation. As the investigation progresses, you will fine-tune the hypothesis to incorporate what you learn about the agent, source, means of transmission, and how the illnesses occurred. At some point in the investigation the hypothesis will be tested. The data will be analyzed and we'll find out if our assumptions hold water. If they don't, we have to rethink our assumptions and start again.

A hypothesis is a statement that can be tested and refuted. The term hypothesis has both a research meaning and a statistical meaning. A research hypothesis is a hunch or a suspicion based upon careful observations. This "hunch" offers a plausible explanation of how an event occurred. In the drama, for example, the outbreak team suspected that individuals attending the banquet at Sandy Grove became ill after eating Caesar salad that was possibly contaminated with Norwalk virus.

Now, a statistical hypothesis is used to determine if there are associations between variables. There are two types of statistical hypotheses: the null hypothesis and the alternative hypothesis.

Null Hypothesis: no difference, no association, measure of association equals 1.

The null hypothesis is specifically worded to say there is no difference in the rates of illness between the exposed and unexposed groups. The null hypothesis implies that the relative risk or odds ratio is equal to 1.0. Accepting the null hypothesis implies that the results of a statistical test are due to chance and not to any real differences between groups.

Alternative Hypothesis: there is a difference, there is an association, measure of association does not equal 1.0

The alternative hypothesis says there is a difference in the rates of illness between groups. So the two hypotheses are different. The null and alternative hypotheses take opposite positions. In other words, they're mutually exclusive and complementary.

The alternative hypothesis implies that the relative risk or odds ratio is either less than one, or greater than one, but does not equal one. Once again, the null hypothesis says there is no association and the alternative hypothesis states there **is** an association.

In a statistical analysis the null hypothesis is tested but statistical testing is not straightforward. For example, you want to know if there is an association between exposure and illness but you test the null hypothesis which states there is no association. Then, based on your results, you either reject or fail to reject the null hypothesis.

In the drama, for example, the null hypothesis states that there was no association between illness and consuming the Caesar salad. Based on the statistical analysis the null hypothesis was rejected and the alternative hypothesis was adopted. It's important to state both the null and alternative before beginning the analysis so you'll be able to interpret your results.

The probability associated with a statistical hypothesis will help you decide if there's a significant association between exposure and illness or if the results are due to chance. By a chance association, I mean that any apparent association is just a coincidence.

Probability is also referred to as the p-value. The p-value is a measure of the chance the observed results would occur if the null hypothesis were true. We use statistical methods and p-value to determine how much confidence to place in the conclusions we reach. A small p-value, say, less than.05 means that something other than chance is likely to explain the results.

The cut off of.05 is arbitrary. You must consider many factors, like sample size and quality of data, and then decide how much consideration to give to a single test result. The.05 cutoff is accepted by the statistical field. If another cut off is used, then you must be prepared to justify why. Here's an example. Say you believe in the null hypothesis, i.e., there's no association between exposure and illness. Then you do the statistical test and learn there's less than a 5-percent chance that the null hypothesis is correct. The data does not support the null hypothesis. So, based on the low probability of getting the results you would reject the null hypothesis and defer to the alternative which says there is an association.

Even if your statistical results show an association, you still can't automatically assume a cause-effect relationship between exposure and illness. The association could reflect biases in the design, conduct, or analysis of the study. Or, the statistical results could reflect a true but non-causal relationship, that is, you don't really have a cause-effect relationship. There's more to this than just numbers. To be able to infer causality, factors such as consistency of the findings with other studies, temporal relationship, and biological plausibility must all be considered.

Criteria for inferring a causal relationship between an implicated food and illness.

- Strength of association.

- Consistency of the observed association.
- Biological plausibility of the observed association.
- Temporal sequence of events.
- Dose-response relationships.

Here are some of the criteria used to determine if you might have a causal relationship between a food and an illness.

Strength of association refers to the relative risk or odds ratio. We just talked about that. Ask yourself, “do I have evidence of a significant association between exposure to the food and illness?” Finding an association using different study designs, different populations, and different settings supports an argument for a causal connection. You have consistency. If experience shows the implicated food has previously served as the route of transmission of the pathogen, the current findings more strongly support a causal association. To claim a causal association, the association must be biologically possible and exposure to the product must come before, not after, the onset of illness.

A dose-response relationship strengthens the argument for a causal association. For our purpose, dose refers to the amount of pathogen in the food and response refers to illness. You have a dose-response relationship when the number of ill people increases as food consumption increases.

An “odds ratio” of 1.0 means there was no association between exposure and illness. Ratios significantly greater or less than 1.0 may support the alternative hypothesis. Now, what is the probability associated with getting a certain relative risk or odds ratio?

Compute a Chi Square Statistic

The Chi-Square is a test of statistical significance that can tell you the probability of getting a relative risk or odds ratio value by chance alone. The Chi Square is a tool you can use to help you determine if your results are due to chance.

The Chi-Square looks at the difference between what you observe in the data and what you'd expect to see if there was no association between exposure and illness. To use the Chi-Square statistic we must assume that our study population is really a sample of some larger population and in the larger population, exposure and illness are not associated.

Let’s look at some numbers.

2 X 2 contingency table for an unmatched case-control study design

			Illness Status: Cases	Illness Status: Controls
EXPOSURE	Exposed		13 a	32 b
	Not Exposed		17 c	23 d

Odds Ratio (OR) = (a / c) / (b / d)
= (13 / 17) / (32 / 23)
= 0.55

This is the data we used earlier to calculate an odds-ratio for a case-control study.

2 X 2 table for calculating the Chi Square statistic

		ILLNESS STATUS: Cases	ILLNESS STATUS: Controls	
EXPOSURE	Exposed	13 a	32 b	45 a+b
	Not Exposed	17 c	23 d	40 c+d
		30 a+c	55 b+d	85 N

To compute a Chi-Square, add row and column totals to the table. Our null hypothesis states there's no association between case-control status and exposure. We will reject the null hypothesis if the p-value associated with the Chi-Square is less than.05.

Chi-Square formula and calculation.

$$\text{Chi Sq. (Yates)} = \frac{N\,[\,|(a * d) - (b * c)| - (N/2)\,]^{2}}{(a+b) * (c+d) * (a+c) * (b+d)}$$

$$= \frac{85 * [\,|(13 * 23) - (32 * 17)| - (85 / 2)\,]^{2}}{(\,45\,) * (\,40\,) * (\,30\,) * (\,55\,)}$$

$$= 1.17$$

Here is the Yates corrected Chi-Square formula. Once the Chi Square is calculated for this example, you come up with an answer of 1.17. The probability of getting a value of 1.17 can be determined using a Chi-Square probability distribution table.

P-values Degrees of Freedom*							
df*	.50	.20	.10	.05	.02	.01	.001
Value of the Chi Square Statistic							
1	0.45	1.64	2.71	3.84	5.41	6.64	10.83
2	1.38	3.21	4.61	5.99	7.82	9.21	13.82
3	2.37	4.64	6.25	7.82	9.84	11.35	16.217
-							
-							
-							
30	29.33	36.25	40.26	43.77	47.96	50.89	59.70

Based on: Principles of Epidemiology, 2nd Ed., 12/92.
USDHHS, PHS, CDC. Figure 6.6, page 378.

To use this table, we need to decide how many degrees of freedom we have. The concept of degrees of freedom isn't easy to define. So, without getting into a long and protracted explanation, let's say that for a 2 x 2 contingency table, like the one we are using, use one degree of freedom. We need to look up our calculated value of 1.17 in the table using one degree of freedom. The p-value, our probability, is between.2 and.5. The exact p-value is.278!

The actual value came from the Epi-Info computer program. So, we can say, the probability of obtaining a Chi Square value of 1.17 if the null hypothesis is true, is.278. Chi Square values that occur with less than a.05 probability are considered extreme enough to reject the null hypothesis. It's easy to see.278 is greater than our arbitrary cut-off p-value of.05 , so we accept the null hypothesis and conclude that the Chi Square value of 1.17 is not statistically significant.

In the drama, the outbreak team discussed the 95-percent confidence interval (which is a range of values that has a 95-percent chance of containing the value we are trying to estimate). In other words, if we were to do the exact study 100 times then 95 of the 100 times we would expect to get an estimate within the range of the confidence interval.

The p-value and the confidence interval provide complementary information and like p-values, confidence intervals can be used to reject the null hypothesis. When the p-value is less than.05 then the 95-percent confidence interval will not overlap-one.

Example of EPI-INFO output

```
              Disease

             +       -

    E  +   13       32  = 45    Analysis of Single Table
    X                            OR = 0.55 (0.20 <OR< 1.48)
    P  -   17       23  = 40    RR = 0.68 (0.38 <RR< 1.22)
           __       __    __    Taylor Series 95% CI for RR


Total      30       55    85    Ignore RR if case-control study

                                    Chi-Square   p-value
                    Uncorrected     :   1.72       0.1899
                    Mantel-Haenszel :   1.70       0.1925
                    Yates corrected :   1.17       0.2786

  For More Strata;  <Enter> No More Strata; F10 Quit
```

When we began talking about statistics we said there are computer programs that would calculate relative risks, odds ratios, the Yates corrected Chi-Square, confidence intervals and p-values for you.

This is what the 2-by-2 table output from the Epi Info software program looks like. Earlier we calculated the odds ratio and the Yates corrected Chi-Square. As you can see our calculations agree with the computer generated results.

We used the Yates corrected Chi-Square because it is more "conservative" than other forms of the Chi-Square test.

Conservative means the Yates corrected Chi-Square value is less than the uncorrected or Mantel-Haenszel Chi-Square values. Again, without getting into a detailed explanation of statistics, let's point out another feature of the Epi-Info computer program. Epi-Info will compute a Fisher Exact test when the expected frequency of a 2-by-2 table cell is less than five. Results of the Fishers Exact test are not shown in this graphic but the Fisher Exact test can be used to evaluate any 2-by-2 table. Like the Chi-Square the Fisher Exact test is a hypothesis test; the null hypothesis states that the row and column variables are unrelated. The Fisher Exact test evaluates all possible 2-by-2 tables which have the same row and column totals as the observed data and gives the overall probability of obtaining a difference between groups at least as large as the observed difference when the null hypothesis is true. Results of the Fisher Exact test and the Chi-Square test are usually similar.

We've only begun to discuss the analysis of epidemiologic data. There are many topics we haven't touched on. It is our hope that when your team meets to plan for the next outbreak you will continue the discussion of descriptive and analytical epidemiology.

Ideally, by the time you're ready to close-out a foodborne illness outbreak investigation, the environmental, laboratory, and epidemiological evidence are all pointing to the same conclusions. Environmental, stool, serum, and suspect food samples would have been submitted to the lab. At the facility, leftovers would have been appropriately detained, and the activity of sick employees would have been restricted. The investigator would have a list of persons attending the event and anyone that took leftovers home would have been informed about the contaminated food.

In general, the environmental assessment would be complete. The integrity of samples submitted to the lab would have been maintained and the possibility of sample contamination would have been ruled out. The lab would have identified the same pathogen and serotype in the implicated food, cases and where relevant, food workers. If blood samples were collected, the lab would have reported an increased antibody titer in sera from cases whose clinical symptoms were consistent with those produced by the agent.

All of the “ills and wells” associated with the event would have been interviewed and case findings would be complete. An outbreak specific questionnaire would have been used to collect data. Symptoms and incubation times would be known. A line-list, epidemic curve, and attack rate table would have been developed. The relative risk and confidence interval would be known. The outbreak team would have had regular meetings to discuss the hypothesis and case definition. The hypothesis and statistical results would have been reviewed and compared to known facts. The team would have reviewed criteria for causality and developed final conclusions. The conclusions would address the source of the outbreak, transmission of the agent, and account for how the outbreak occurred.

If appropriate, a product traceback would be underway to remove the product from distribution. Finally, recommendations will have been made to prevent similar outbreaks from occurring in the future. What we’ve described is an ideal situation but what would you suggest if lab conformation of the pathogen is not available?

Criteria for action based on epi data without lab confirmation. .

- Waiting for laboratory confirmation would result in more people becoming ill.
- Epi evidence shows a strong association between the illness and product.
- The epi studies were conducted appropriately.
- There is a low probability that the association between the illness and implicated product is due to chance.
- Several widely accepted criteria for causality are present.

Laboratory confirmation of the agent in the implicated product is certainly desirable. However, if laboratory evidence is not available, removal of the product from the market should be considered if waiting for laboratory confirmation would result in more people becoming ill, PROVIDED THAT: the epi-evidence shows a strong association between the illness and product; epi-studies were conducted appropriately and show a low probability that the

association is due to chance; and, the presence of several widely accepted criteria for causality would strengthen the argument for removing the product.

These are guidelines for taking action based on only EPI evidence, but if you have to defend your actions in court then you better be sure to have complete documentation. Also, remember the final outbreak reports may be used in litigation to justify an intervention.

Final Report

Objective

Upon completion of this module, participants will be able to:

- Discuss the design and purpose for the final report of an outbreak investigation.
- Be familiar with recent CDC outbreak data.

Before you develop the final report required by your department or agency, be alert to some basic rules on reporting. Be objective and factual, as well as thorough and accurate. Inform the reader so they can clearly see the significant parts of the investigation. Write clearly and to the point. Sentences should be short and uncomplicated. The use of pronouns should be kept to a minimum. Individuals involved in the investigation, are usually identified by position and relationship to the outbreak, not by name. Avoid any temptation towards over-emphasis, exaggeration, or emotion. The report should be a complete account, in plain English.

What format should you use and what should the final report contain? There are several styles, but we'll view the report as a biological research paper. It includes a general presentation of all the environmental, epidemiological and laboratory findings. Exactly how the final report is structured will vary. But let's walk through an outline in the manual that could be used to summarize the logic behind a foodborne outbreak investigation.

Let's begin with a "cover page" that identifies fundamental information: name of the outbreak; investigating agency; whether a single or multiple exposures occurred; dates of the outbreak; then the departments or agencies involved, and sometimes the names and titles of the investigators. Finally in this section, state who prepared the report.

After the cover page comes the main body of the report, which consists of a number of sections: summary, methods, results, followed by conclusions and recommendations.

The summary section provides a concise description of the investigation: dates, who first reported the outbreak, the suspect or identified agent, operation or facility, who became ill and the number, the number of people interviewed, predominant symptoms, incubation period, duration of illness, number of deaths or hospitalizations, the actual or possible source or vehicle, laboratory results, contributing factors, control measures taken during the outbreak, and actions taken to prevent re-occurrences.

Example of Final Report Outline

Cover Page

- Name of outbreak
- Investigating agency
- Date(s) of the outbreak

- Investigator's name & title
- Report prepared by

Summary

- Date of outbreak
- Outbreak was first reported by
- Agent or suspect agent
- Facility, size and type of food service
- Who and number ill
- Number interviewed
- Predominant symptoms
- Incubation period (median, range)
- Duration of illness (median, range)
- Number of deaths or hospitalizations
- Source or vehicle
- Laboratory results
- Contributing factors
- Control measures instituted during investigation
- Actions taken to prevent re-occurrence

Methods

- Case definition
- Hypothesis
- Questionnaire
- Food preparation review
- Attack rates
- Statistical significance

- Clinical/environmental samples

Results

- Epidemiology
- Environmental
- Lab
- Size & duration
- Statistical significance of suspect food(s)

Conclusions, Discussions & Rationale

- Agents
- Contributing factor(s)

Recommendations

- Corrective measures implemented
- Future prevention measures
- Be objective and factual
- Inform the reader
- Write clearly and to the point
- Individuals identified by position and relationship: not by name
- Avoid over-emphasis, exaggeration, or emotion

Also, the report should explain the methods, or how the investigation was carried out. This includes our case definition, hypothesis, questionnaire and interviews, food preparation procedures, attack rates and statistical significance, along with food, environmental and clinical samples. The report also includes the results of the investigation: epidemiological, environmental and laboratory findings. Finally, the report wraps up with a discussion of conclusions and recommendations based on the investigation.

In addition to developing the final report, some regulatory agencies may also be obliged to develop a facility inspection report. This document is typically limited to factors associated with the facility. An outbreak investigation is more than a GMP or “good manufacturing practices” inspection of an establishment. For follow-up there is a particular emphasis on the environmental considerations that may have contributed to an outbreak. The purpose of such a

report is to clarify evidence that has the potential for regulatory response. For FDA this is discussed in the Inspection Operations Manual, Section 593.

The Centers for Disease Control and Prevention has developed forms for the reporting of foodborne outbreaks back to CDC. For the most current copy, contact your state epidemiologist. New forms are being developed to expand the reporting categories of contamination, proliferation, and survival. From successful investigations and effective follow-ups, we have prevented additional outbreaks. For example, raw shell eggs are now refrigerated, hamburger cooking temperatures have been increased and we're now beginning to understand more about cyclospora and other pathogens. Knowledge gained from these reports keeps our food safety regulations and policies current with new findings.

CDC has compiled data on outbreaks with confirmed etiology from 1988 to 1992. These outbreaks have laboratory confirmation of the agent, and account for approximately one third of all outbreaks that are reported. Of the remaining outbreaks reported, approximately one third are of suspect etiology, lacking laboratory confirmation. The remaining one third are of unknown cause.

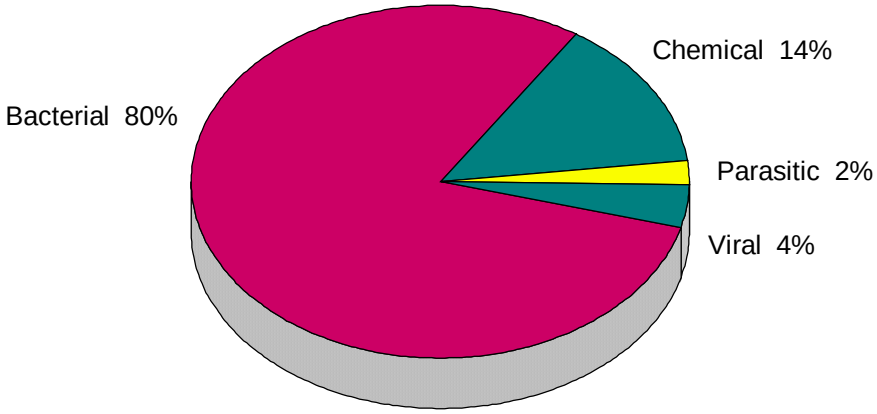
Let's look at the recent CDC data to get a national perspective on foodborne illness, 2% of all these foodborne outbreaks are of parasitic origin, viruses account for 4%, and chemical contamination 14%. Contrast that with bacterial foodborne outbreaks, the biggest slice, which make up 80% of the outbreaks of known etiology. The percentages may differ regionally, but the overall trends are probably similar. More recent information, not reflected in this data, indicates that viruses are playing a more significant role in foodborne illnesses and parasites such as cyclospora are also emerging as important agents. Also, recent CDC active surveillance data is showing the bacteria *Campylobacter* as one of the most common causes of foodborne illness, even surpassing *Salmonella*.

The majority of the bacterial outbreaks occur in delis, cafeterias and restaurants at the retail level. Don't worry about exact percentages; it's the big picture that is important. Now the question is "What are the contributing factors to these outbreaks?"

The graph here shows the Factors Contributing to Confirmed Bacterial Foodborne Outbreaks. The categories are: improper holding temperatures, poor personal hygiene of food workers, inadequate cooking, contaminated equipment, and unsafe sources. Remember, an outbreak can have multiple contributing factors.

For example, a menu item comes in from an unapproved source, prepared by a sick employee with contaminated equipment, and inadequately cooked and transferred to a steam table at 98^{O}F before being served. From our efforts in gathering foodborne illness data, we're beginning to learn about some of the long term, chronic effects that some foodborne pathogens can cause. For example, Guillain Barré Syndrome, a peripheral nerve disorder can be associated with *Campylobacter* jejuni; Reiter Syndrome has been associated with *Yersinia*, *Shigella*, *Salmonella* and *Campylobacter* and an association has been made between Hemolytic Uremic Syndrome and *E. Coli* O157:H7

Confirmed Etiology for Foodborne Outbreaks for 1988-1992 (%)



CDC Surviellance for Foodborne Disease Outbreak, 1988-1992
MMWR, Oct 25, 1996/Vol 45/No. SS-5

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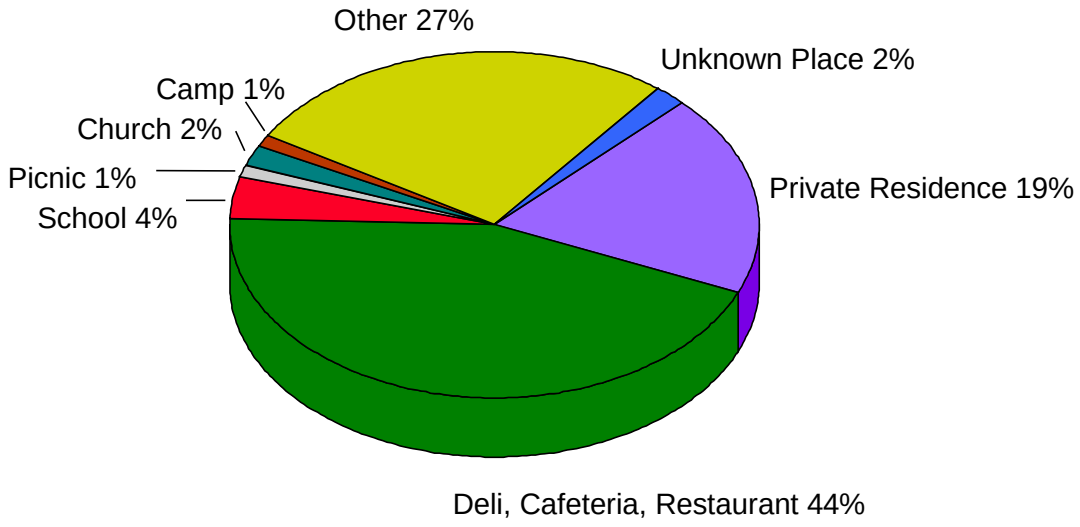
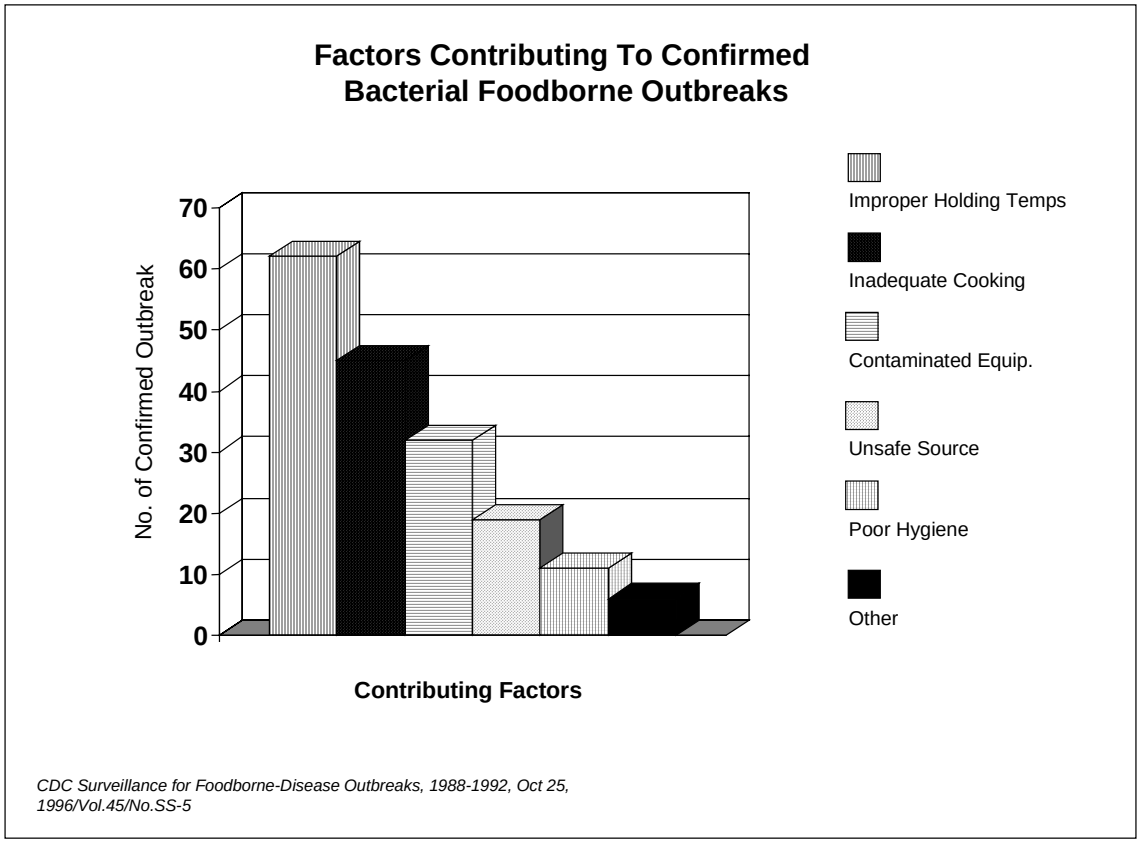
Confirmed Bacterial Foodborne Outbreaks by Location Where Food Was Eaten (%)



CDC Surveillance fo Foodborne Disease Outbreaks, 1988-1992
MMWR, Oct 25, 1996/Vol 45/No. SS-5



CDC Surveillance for Foodborne-Disease Outbreaks, 1988-1992, Oct 25, 1996/Vol.45/No.SS-5

The graph here shows the Factors Contributing to Confirmed Bacterial Foodborne Outbreaks. The categories are: improper holding temperatures, poor personal hygiene of food workers, inadequate cooking, contaminated equipment, and unsafe sources. Remember, an outbreak can have multiple contributing factors.

For example, a menu item comes in from an unapproved source, prepared by a sick employee with contaminated equipment, and inadequately cooked and transferred to a steam table at 98^{O}F before being served. From our efforts in gathering foodborne illness data, we're beginning to learn about some of the long term, chronic effects that some foodborne pathogens can cause. For example, Guillain Barré Syndrome, a peripheral nerve disorder can be associated with *Campylobacter* jejuni; Reiter Syndrome has been associated with *Yersinia*, *Shigella*, *Salmonella* and *Campylobacter* and an association has been made between Hemolytic Uremic Syndrome and *E. Coli* O157:H7

TABLE X

Confirmed, Suspected, & Unknown Etiology Foodborne Disease Outbreaks

by Method of Preparation, Significant Ingredient, Agent and Contributing Factor

Cumulative: 01/01/80 through 12/31/95

New York State Department of Health

COOK/SERVE FOODS

SIGNIFICANT INGREDIENT	AGENTS			CONTRIBUTING FACTORS	
EGGS	(27)	*GASTROINTESTINAL VIRUS (GI)	(1)o	INADEQUATE REFRIGERATION	(23)*
		SALMONELLA	(26)	INADEQUATE NOT-HOLDING	(4)
				FOOD PREP SEVERAL HOURS BEFORE SERVING	(7)
				INADEQUATE COOKING	(20)
				INADEQUATE REHEATING	(5)
				CONTAMINATED INGREDIENTS	(22)
				CROSS-CONTAMINATION	(2)
				HAND CONTACT W/ IMPLICATED FOOD	(2)
				CONSUMPTION: RAW/LTLY HEATED (ANIMAL ORI	(3)
BEEF	(21)	ESCHERICHIA COLI 0157:H7	(5)	INADEQUATE REFRIGERATION	(3)
		CAMPYLOBACTER	(2)	INADEOUATE COOKING	(9)
		CLOSTRIDIUM PERFRINGENS	(2)	CONTAMINATED INGREDIENTS	(3)
		SALMONELLA	(5)	CROSS-CONTAMINATION	(3)
		OTHER CHEMICAL	(1)	UNKNOWN	(10)
		UNKNOWN	(6)		
PORK	(10)	SALMONELLA	(2)	INADEQUATE REFRIGERATION	(2)
		STAPHYLOCOCCUS AUREUS	(2)	INADEQUATE NOT-HOLDING	(1)
		TRICHINELLA SPIRALIS	(4)	INADEQUATE COOKING	(5)
		YERSINIA ENTEROLYTICA	(2)	UNAPPROVED SOURCE	(1)
				CONTAMINATED INGREDIENTS	(3)
				CROSS-CONTAMINATION	(2)
				UNCLEAN EQUIPMENT	(1)
				UNKNOWN	(2)

SIGNIFICANT INGREDIENT	AGENTS			CONTRIBUTING FACTORS	
POULTRY	(20)	CAMPYL0BACTER	(1)	INADEQUATE REFRIGERATION	(5)
		CLOSTRIDIUM PERFRINGENS	(1)	INADEQUATE HOT-HOLDING	(2)
		SALMONELLA	(6)	FOOD PREP SEVERAL HOURS BEFORE SERVING	(1)
		STAPHYLOCOCCUS AUREUS	(2)	INADEQUATE-COOKING	(7)
		UNKNOWN	(10)	CONTAMINATED INGREDIENTS	(1)
				INFECTED PERSON	(1)
				CROSS-CONTAMINATION	(4)
				UNCLEAN EQUIPMENT	(3)
				IMPROPER COOLING	(1)
				HAND CONTACT W/ IMPLICATED FOOD	(1)
				UNKNOWN	(9)
FIN FISH	(3)	OTHER CHEMICAL	(1)	NATURAL TOXICANT	(1)
		UNKNOWN	(2)	UNKNOWN	(2)
SHELLFISH	(1)	GASTROINTESTINAL VIRUS (GI)	(1)	UNKNOWN	(1)
OTHER SEAFOOD	(11)	GASTROINTESTINAL VIRUS (GI)	(1)	INADEQUATE REFRIGERATION	(1)
		PLESIOMONAS SHIGELLOIDES	(1)	UNKNOWN	(10)
		SALMONELLA	(2)		
		STAPHYLOCOCCUS AUREUS	(1)		
		OTHER CHEMICAL	(1)		
		UNKNOWN	(5)		
STARCHY FOODS	(2)	BACILLUS CEREUS	(1)	INADEQUATE REFRIGERATION	(1)
		STAPHYLOCOCCUS AUREUS	(1)	INADEGUATE HOT-HOLDING	(1)
				UNCLEAN EQUIPMENT	(1)
				IMPROPER COOLING	(1)
				OTHER	(1)
DAIRY	(1)	GASTROINTESTINAL VIRUS (GI)	(1)	UNKNOWN	(1)
INFECTED WORKER	(3)	SALMONELLA	(2)	INFECTED PERSON	(3)
		SHIGELLA	(1)		

SIGNIFICANT INGREDIENT	AGENTS			CONTRIBUTING FACTORS	
NO SPECIFIC INGREDIENT	(36)	CLOSTRIDIUM PERFRINGENS	(2)	INADEQUATE REFRIGERATION	(3)
		GASTROINTESTINAL VIRUS (GI)	(2)	INADEQUATE NOT-HOLDING	(4)
		MSG	(1)	INADEOUATE COOKING	(2)
		SALMONELLA	(2)	INADEQUATE REHEATING	(1)
		STAPHYLOCOCCUS AUREUS	(5)	UNCLEAN EQUIPMENT	(1)
		OTHER CHEMICAL	(2)	ADDED POISONOUS CHEMICALS	(1)
		UNKNOWN	(22)	IMPROPER COOLING	(1)
				UNKNOWN	(28)

ROASTED MEAT/POULTRY

SIGNIFICANT INGREDIENT	AGENTS			CONTRIBUTING FACTORS	
BEEF	(35)	CLOSTRIDIUM PERFRINGENS	(15)	INADEOUATE REFRIGERATION	(4)
		GASTROINTESTINAL VIRUS (GI)	(4)	INADEOUATE NOT-HOLDING	(11)
		SALMONELLA	(3)	FOOD PREP SEVERAL HOURS BEFORE SERVING	(7)
		STAPHYLOCOCCUS AUREUS	(1)	INADEGUATE COOKING	(5)
		UNKNOWN	(12)	INADEQUATE REHEATING	(9)
				CROSS-CONTAMINATION	(2)
				UNCLEAN EGUIPMENT	(2)
				IMPROPER COOLING	(5)
				UNKNOWN	(13)
PORK	(13)	CAMPYLOBACTER	(1)	INADEQUATE REFRIGERATION	(2)
		SALMONELLA	(2)	FOOD PREP SEVERAL HOURS BEFORE SERVING	(1)
		TRICHINELLA SPIRALIS	(2)	INADEQUATE COOKING	(4)
		UNKNOWN		INADEQUATE REHEATING	(2)
				CONTAMINATED INGREDIENTS	(1)
				INFECTED PERSON	(1)
				CROSS-CONTAMINATION	(2)
				UNCLEAN EQUIPMENT	(1)
				IMPROPER COOLING	(5)
				HAND CONTACT W/ IMPLICATED FOOD	(1)
				UNKNOWN	(1)
POULTRY	(37)	BACILLUS CEREUS	(1)	INADEQUATE REFRIGERATION	(8)
		BACILLUS SUBTILIS	(1)	INADEQUATE HOT-HOLDING	(7)
		CAMPYLOBACTER	(4)	FOOD PREP SEVERAL HOURS BEFORE SERVING	(7)
		CLOSTRIDILIM PERFRINGENS	(7)	INADEQUATE COOKING	(14)
		SALMONELLA	(18)	INADEQUATE REHEATING	(5)
		STAPHYLOCOCCUS AUREUS	(1)	CONTAMINATED INGREDIENTS	(2)
		UNKNOWN	(5)	INFECTED PERSON	(1)
				CROSS-CONTAMINATION	(2)
				UNCLEAN EQUIPMENT	(1)
				IMPROPER COOLING	(9)
				HAND CONTACT W/ IMPLICATED FOOD	(2)
				UNKNOWN	(10)
INFECTED WORKER	(2)	SALMONELLA	(1)	INADEQUATE NOT-HOLDING	(1)
		UNKNOWN	(1)	INFECTED PERSON	(1)
				CROSS-CONTAMINATION	(1)

SOLID MASSES OF POTENTIALLY HAZARDOUS FOODS

SIGNIFICANT INGREDIENT	AGENTS			CONTRIBUTING FACTORS	
EGGS	(20)	SALMONELLA	(20)	INADEQUATE REFRIGERATION	(15)
				INADEQUATE HOT-HOLDING	(3)
				FOOD PREP SEVERAL HOURS BEFORE SERVING	(1)
				INADEQUATE-COOKING	(20)
				INADEQUATE REHEATING	(6)
				CONTAMINATED INGREDIENTS	(14)
				CROSS-CONTAMINATION	(2)
				UNCLEAN EOUIPMENT	(2)
				IMPROPER COOLING	(5)
				HAND CONTACT W/ IMPLICATED FOOD	(1)
BEEF	(20)	FECAL STREPTOCOCCUS	(1)	INADEQUATE REFRIGERATION	(5)
		BACILLUS CEREUS	(1)	INADEQUATE HOT-HOLDING	(7)
		CLOSTRIDIUM PERFRINGENS	(14)	FOOD PREP SEVERAL HOURS BEFORE SERVING	(1)
		SALMONELLA	(2)	INADEQUATE COOKING	(2)
		UNKNOWN	(2)	INADEQUATE REHEATING	(7)
				INFECTED PERSON	(1)

There are different ways of organizing outbreak data. For one example, let's see how the state of New York has compiled their results of foodborne outbreak investigations from 1980 through 1995. They sorted their outbreak findings by method of preparation for food type, significant ingredient, causative agent, and contributing factors.

The data was organized into broad categories or "methods of preparation" that are common or typical ways in which menu items are prepared for service. For example, cook/serve, solid masses of potentially hazardous food, sandwiches, baked goods, and foods eaten raw or lightly cooked. These categories were then subdivided by significant ingredient, to identify the ingredient that predominates or characterizes the dish that may have harbored the agent. These significant ingredients are then broken down by contributing factors that resulted in the contamination, survival, or growth of the agent. The category, "roasted meat/poultry" is broken down into sections by significant ingredient, beef, pork, and poultry**.**

Let's look under the section for beef as the significant ingredient. First, we see the number 35 in parentheses. This is the total number of roasted beef outbreaks reported during the time period. Looking under the column "Agents" the 35 outbreaks are broken down by the five different agents attributable to the outbreaks.

The outbreaks are further broken down by contributing factors in the next column. Remember that an outbreak can result from multiple contributing factors and sometimes these factors cannot be determined during the investigation.

Summarizing data by significant ingredients or food types, agents, and contributing factors from foodborne disease outbreaks provides us with insights for our work in investigations. It's also an excellent way to focus our prevention efforts.

Recap from a laboratory perspective; comparison of the foodborne illness outbreak investigation to the distillation process.

Let's begin with the Bunsen burner. The energy in the flame represents the department's surveillance procedures. The Ehrlen Meyer flask contains the surveillance log and illness reports. Now, we fire up the Bunsen burner to provide sufficient energy to process the data so all relevant information is dissolved into solution.

As the pool of data heats up, the essence of the illness complaints is vaporized.

The vapor flows into the data distillation tube where the information is refined for analysis and interpretation. Symptoms, along with clinical and confirmed diagnoses are evaluated and compared for time, place and person associations.

As associations are made and it appears that a foodborne outbreak may have been detected, the vapor begins to condense at the top of the distillation tube providing concentrated raw data. As the surveillance essence collects and flows down the tube, the investigation team comes together and development of the initial working case definition and hypothesis begins.

The data distills into the foodborne illness investigation beaker. Depending on the volume, composition and reactivity of the data the appropriate policies have to be added in the right amount from the dropper. These policies act as a catalyst to stimulate the investigation to the appropriate response level. Also, and very important, don't forget to stabilize any reactions that may be occurring. You don't want an explosion. So, from the burette of common sense, make sure a good measure is added to the investigation to help bring an end to the outbreak.

There are many chemical interactions taking place during the investigation. Information from environmental findings, food prep reviews, food and clinical samples, EPI findings from outbreak specific questionnaires, case findings, press notification, statistical and other epidemiological evidence, and laboratory findings are all mixed. The analysis and interpretation rise to the top of the investigation beaker and hopefully explain the outbreak. Irrelevant facts and misinformation settle to the bottom.

The important details must be decanted to the final report for a concise summary of the investigation and conclusions. We have developed the expertise to resolve various outbreaks because people have taken the time over the years to share their experiences. Writing them down has helped to protect public health by: documenting statistics on outbreaks, information about new pathogens, or new environments for existing pathogens. Of course, we also need to explain these events to local health officials, other cooperating agencies, and the public.

Glossary

Abridged definitions for terms used in the Foodborne Illness Investigations course.

(The following definitions are for quick reference purposes only. For more precise and complete definitions refer to an Epidemiology reference book).

Accuracy	the extent to which a measurement reflects the true value.
Attack rate	the proportion of those exposed that become ill.
Attack rate table	a format for summarizing the relationship between consumption of specific foods and illness data.
Bias	anything that leads to conclusions that are systematically different from the truth.
Carrier	a carrier harbors and is able to transmit a pathogen but a carrier has no clinical signs of infection.
Case fatality rate	the proportion of people who die among those infected.
Case-control design	an observational study design using a not-well-defined population. Subjects are sampled based upon illness status. Those with the illness are called cases and those free of the illness are called controls. The investigator then determines if each case and each control subject had the exposure of interest.
Causality	some of the criteria for inferring a causal relationship between an implicated food and illness include strength of association, consistency of the observed association, biological plausibility of the observed association, temporal sequence of events, effect of removing the exposure, dose-response relationships, and the exclusion of alternative explanations.
Chi Square test	a test of statistical significance. A Chi Square test looks at the difference between what we observe in the data and what we would expect if the exposure was not associated with illness.
Cohort design	an observational study design using a well-defined population. Subjects are sampled based upon exposure status. Subjects are then monitored to determine the rates of illness that develop in each exposure group.
Colonized	a carrier state in which a person is not really infected with the pathogen but simply has it on the skin or mucous membrane (e.g., S. aureus).
Common source exposure	illness spreads from a common source of the pathogen.
Communicable disease	an infectious disease transmitted from an infected person, animal, or reservoir to a susceptible host through an intermediate plant, animal, or the inanimate environment.
Confidence interval	a confidence interval is a range of values that has a specified probability of containing the true relative risk or odds ratio. One is, for example, 95% "confident" that the true value is within this interval.
Contagious disease	"highly infectious" disease.
Contingency table	a way to organize exposure and illness data.
Degrees of freedom	calculated as the sample size minus the number of estimated parameters. For a 2X2 contingency table use one degree of freedom.
Denominator	often refers to the "population at risk".
Dose	the number of microorganisms that a person is exposed to.
Duration	how long the illness lasts.
Endemic	disease that lingers at about the same incidence for a long time.

Epidemic	cases of illness in excess of expectancy.
Epidemic curve	graphic format used to characterize an outbreak's magnitude and time trend. See Common source outbreak, Propagated outbreak, Mixed outbreak
Experimental design	a study design used when the exposure has not occurred. Subjects are randomized and either exposed to a treatment or remain unexposed. Then subjects are observed to determine rates of illness among exposed and unexposed.
Exposed	contact with an infectious agent in a way that may result in illness.
Exposure	a factor (variable) that increases (decreases) occurrence of a disease.
Herd immunity	immunity of a group.
Generation time	the time between exposure and when a host is most infectious to others.
Immune	refers to someone who shows no clinical signs of infection after exposure to a pathogen.
Incidence rate	the number who become ill during a defined time period divided by the number of people exposed to the risk during the time period.
Incubation period	the time from when a person is infected until he develops symptoms of illness.
Index case	the first case to come to the attention of the investigator.
Infected	an exposed person reacts serologically to the infectious agent. The infected person may have a clinical or a subclinical infection.
Infectious period	the time period during which a person can transmit a disease.
Infectivity	the microorganism's ability to enter, survive, and multiply in a host.
Latent period	the time between exposure and the appearance of symptoms.
Line listing	a format used to organize all the data, for all of the subjects, on a single spreadsheet. The line listing helps to characterize an outbreak in terms of time, place, and person.
Mean	the average of all values calculated as the total of the individual values divided by the number of values in the data set.
Median	the middle value in a range of values that have been ordered from the minimum to the maximum value (i.e. half the values are below the median and half are above the median).
Mixed epidemics	epidemics that involve a common exposure to an infectious agent and secondary spread to other individuals.
Mode	the value that occurs most often in a data set.
Natural booster	refers to a person whose antibody titre increases after exposure to a pathogen they are immune to. Numerator
often refers to persons "with a particular characteristic".	
Odds ratio	odds of being a case and being exposed divided by the odds of being a control and being exposed. Calculate an odds ratio when you have interviewed only a portion of the people exposed to a foodborne illness. The odds ratio is a good approximation of the relative risk when illness is rare (say, under 2% of the total sample size) and the sample size is large.
Outcome	(for our purposes); illness caused by a pathogen in food.
Pathogenicity	the degree of disease-evoking power of a microorganism to produce clinically apparent disease in an infected person.
Point source epidemic	see common source exposure.
Prevalence	the number of people who have a disease at a specific time.

Primary case	the person who brings the disease into a group of people. The primary case is not necessarily the index case.
P-value	a measure of how likely the observed results would occur when there is no real association between a food and an illness (i.e. how likely the observed results would occur by chance alone).
Progressive epidemic	the pathogenic agent is transferred from one host to another.
Propagative epidemic	see progressive epidemic.
Questionnaire	a set of questions used to collect information. Typically questions can be grouped into the following categories: identifying, demographic, clinical, risk, and reporter information.
Range	the interval between the minimum and the maximum values in a distribution.
Relative risk	risk of illness in the exposed group divided by the risk of illness in the unexposed group. Calculate the relative risk when you have interviewed everyone or almost everyone associated with a foodborne illness event.
Reliability	refers to the consistency of a measurement when repeated on the same subjects.
Reproductive rate	the potential for a contagious disease to spread in a population. The potential for spread is based upon the proportion of the population that is immune, the probability of transmission, the frequency of contacts in the population, and the length of the infectious period.
Reservoir	a place where a pathogen lives and multiplies outside man.
Secondary cases	persons infected by the primary case or other cases.
Sensitivity	a measurement of the proportion of those who truly have the exposure who are correctly classified as exposed.
Seroprevalence	the percentage of a population that have a particular serologic marker.
Source	the object, animal, or person from which the infection is acquired.
Specificity	a measurement of the proportion of those who are truly unexposed who are classified as unexposed.
Spot map	a map used to characterize the outbreak by place.
Standard deviation	a measure of variation in the data. A standard deviation is the square root of the average squared deviations from the mean. It is equal to the positive square root of the variance.
Significance test	a test of statistical significance shows how likely one is to get a measure of association as strong as the observed one if there is no difference between the groups.
Surveillance	Monitoring to detect changes in trends.
Susceptibles	persons who are not immune to a disease but could be infected if exposed.
Validity	extend to which the exposure variable measures the true exposure in the population.
Variance	A measure of the variation in the data. Variance is the sum of the squared deviations from the mean, divided by the number of degrees of freedom in the data set.
Vector	usually an animal or insect that transmits a pathogen from an infected person to a susceptible person.

Virulence	the degree of disease-evoking power, pathogenicity, of a microorganism in a host.
Zoonoses	infections that spread from vertebrate animals to people. (Note infections that spread without an animal reservoir, either from person to person or insects to people, are not called zoonoses.)